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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

COUNTY OF SAN MATEO, CALIFORNIA, Plaintiff, v. **PURDUE PHARMA L.P.;** **PURDUE PHARMA INC.;** **PURDUE FREDERICK COMPANY;** **PURDUE PRODUCTS L.P.;** **CEPHALON, INC.;** **TEVA PHARMACEUTICAL INDUSTRIES LTD.;** **TEVA PHARMACEUTICALS USA, INC.;**	UNITED STATES DISTRICT COURT CASE NO: **COMPLAINT:** 1. **PUBLIC NUISANCE;** 2. **VIOLATION OF THE CALIFORNIA FALSE ADVERTISING LAW;** 3. **UNFAIR BUSINESS PRACTICES;** 4. **NEGLIGENCE;**

ENDO INTERNATIONAL PLC;
ENDO HEALTH SOLUTIONS, INC.;
ENDO PHARMACEUTICALS INC.;
JANSSEN PHARMACEUTICALS, INC.;
INSYS THERAPEUTICS, INC.;
MALLINCKRODT LLC;
MALLINCKRODT PLC.
JOHNSON & JOHNSON;
WATSON LABORATORIES, INC.;
ACTAVIS LLC;
ACTAVIS PHARMA, INC.;
ALLERGAN FINANCE LLC;
ALLERGAN PLC.;
RICHARD SACKLER;
KATHE SACKLER;
JONATHAN SACKLER;
MORTIMER D.A. SACKLER;
DAVID SACKLER;
ILENE SACKLER LEFCOURT

Defendants.

5. **NEGLIGENT MISREPRESENTATION; and,**

6. **FRAUDULENT CONCEALMENT**

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

1. County of San Mateo ("Plaintiff" or "San Mateo County") hereby brings this action for damages and relief against Defendants Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceuticals Products L.P., Purdue Products L.P., Purdue Pharma Inc., Richard Sackler; Kathe Sackler; Jonathan Sackler; Mortimer D.A. Sackler; David Sackler; Ilene Sackler Lefcourt, Cephalon, Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Endo International plc, Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Janssen Pharmaceuticals, Inc., Johnson & Johnson, Insys Therapeutics, Inc., and Mallinckrodt plc, Mallinckrodt LLC (collectively "Defendants" or "Manufacturer Defendants") for violations of California state law. Defendants are all manufacturers of opioid pharmaceuticals.

I. INTRODUCTION

2. San Mateo County has seen an incredible increase in deaths from opioids in the past few years. Like other counties across the United States, San Mateo County now spends millions of dollars each year dealing with the fallout of the opioid epidemic. San Mateo's ongoing costs include extra expenditures related to drug treatment, emergency room visits, law enforcement, and social services (including for children born opioid-dependent and/or who have parents unable to care for them because of their own respective addictions).

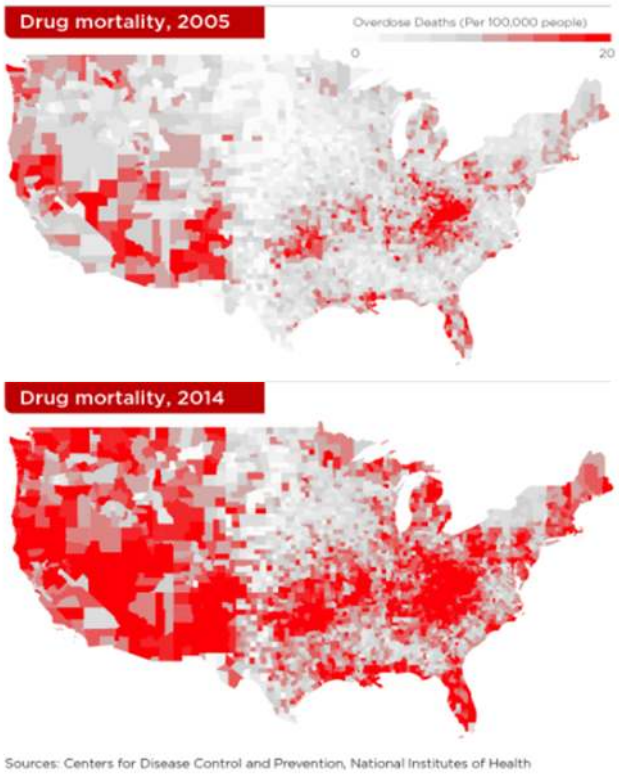
3. More than 200,000 people have died in the United States from overdoses involving prescription opioids in the past twenty years. However, this figure tells only part of the story: Prescription opioid abuse has fueled an ever-growing wildfire of illicit drug abuse in San Mateo County. The wide abuse of illegal opioid compounds directly related to the Opioid Epidemic, such as heroin and counterfeit forms of fentanyl, only adds fuel to the fire, helping turn a serious problem into an epidemic.

4. According to the most recent data available, ***97 San Mateo County residents died in 2017*** from drug-related causes, with ***11 deaths directly tied to heroin use and another 26 deaths directly tied to other opioids***. In ***2016, San Mateo County saw 61 drug-related deaths***, with 11 tied to heroin and 16 tied to other opioids. Between 2010 and 2014, opioids accounted for ***almost half of all filled scheduled drug prescriptions***. In 2015 there were ***hundreds of thousands of opioid***

prescriptions filled in San Mateo County. County health officials estimate that thousands of residents are opioid dependent.

5. According to recent data from the Centers for Disease Control and Prevention ("CDC"), "[a]n in-depth analysis of 2016 United States drug overdose data shows that America's overdose epidemic is spreading geographically and increasing across demographic groups."[1] Drug overdoses killed over 63,000 Americans in 2016. Approximately two-thirds of these deaths (66%) involved a prescription opioid or an illicit opioid. Overdose deaths followed no clear demographic pattern, and saw increased levels in both men and women, all races and ethnicities, and across all levels of urbanization.

6. According to a National Vital Statistics System report published in December 2018 from the Centers for Disease Control and Prevention, Fentanyl is now the drug most frequently involved in overdose deaths in the country.

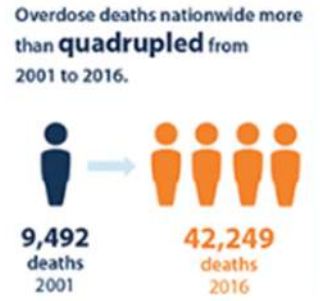


[1] *United States. Drug Overdose Deaths Continue to Rise; Increase Fueled by Synthetic Opioids*, CENTER FOR DISEASE CONTROL AND PREVENTION (2018), available at https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html (Last Accessed June 4, 2018).

7. According to the CDC's most recent analysis, released on March 29, 2018 and based on national 2015-2016 data:

- Overall drug ***overdose death rates increased by 21.5 percent***;
- The overdose death rate from synthetic opioids (other than methadone) more than doubled, likely driven by illicitly manufactured fentanyl;
- The ***prescription opioid-related overdose death rate increased by 10.6 percent***;
- The heroin-related overdose death rate increased by 19.5 percent.

8. The number of opioid prescriptions and the number of opioid deaths are directly and strongly correlated. Since 1999, opioid overdose deaths and the amount of prescription opioids sold has nearly quadrupled.[2]



9. Opioid manufacturers, with the assistance of opioid distributors, send billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and pain clinics, many in San Mateo County. Responsibility for the epidemic lies at the feet of opioid manufacturers, and their co-conspirator distributors, who have engaged in a host of illegal, unfair and fraudulent practices prohibited under California law, causing a public nuisance in San Mateo County.

10. This litigation is focused solely on the companies that manufacture opioids. Practically speaking little difference exists between Defendant Manufacturers and street-corner drug dealers.

11. The current opioid epidemic traces its roots back to 1996 when pharmaceutical company Purdue Pharma released OxyContin and started heavy marketing.[3],[4] That same year, the

[2] *CDC Wonder*, CDC (2018), available at https://wonder.cdc.gov/ (Last Accessed June 4, 2018).
[3] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, AM. J. PUBLIC HEALTH, Feb. 2009, at 99(2): 221–227, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/ (Last Accessed June 4, 2018).
[4] Barry Meier, *Pain Killer: An Empire of Deceit and the Origin of America's Opioid Epidemic* (Random House, 2nd ed. 2018, p. xi).

American Pain Society dubbed pain as "the Fifth Vital Sign."[5] This phrase entered the lexicon through the keynote address at the American Pain Society's 1996 annual conference in Los Angeles. The group went on to trademark the slogan: "Pain: The Fifth Vital Sign." Purdue was a sponsor of the American Pain Society. Within two decades, overdose deaths would exceed the national peaks of gun deaths (occurred in 1993), AIDS deaths (1995), and car crash deaths (1972).[6] Sadly, no peak for this epidemic is currently in sight.

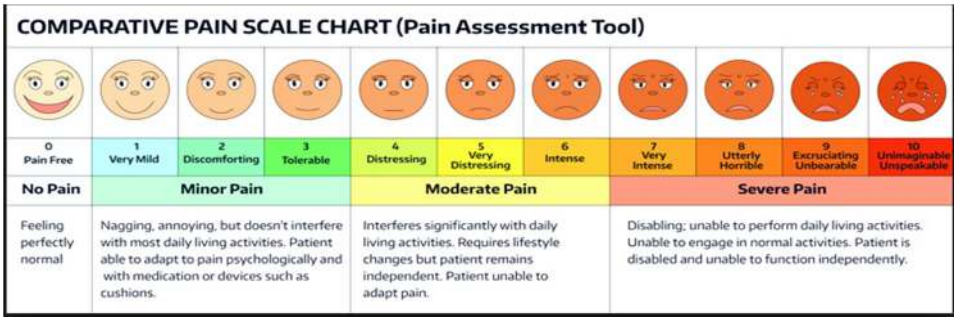
12. Big Pharma (defined below) was behind efforts to recognize pain as the "fifth vital sign" and, along with the Big Three Distributors, mounted a campaign to curb the effectiveness of the United States Drug Enforcement Administration's (DEA) efforts to stem illegal opioid prescriptions.

13. Soon after development of the "Fifth Vital Sign" campaign, pharmaceutical industry front groups began heavily promoting the now familiar 0-10 pain scale and began judging hospitals based on patient satisfaction with pain treatment.[7]

[5] *Pain: Current Understanding of Assessment, Management, and Treatments*, NATIONAL PHARMACEUTICAL COUNCIL (Dec. 2001) at 16-17, available at http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (Last Accessed June 4, 2018).

[6] Josh Katz, *Drug Deaths in America Are Rising Faster Than Ever*, N.Y. TIMES (Jun. 5, 2017), available at https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html?auth=login-smartlock (Last Accessed June 4, 2018).

[7] Julia Lurie, *A Brief, Blood-Boiling History of the Opioid Epidemic*, MOTHER JONES (Feb. 2017), available at https://www.motherjones.com/crime-justice/2017/12/a-brief-blood-boiling-history-of-the-opioid-epidemic/ (Last Accessed June f4, 2018).



14. Nationally, more than three out of five overdose deaths involve opioids[8] — a dangerous, highly addictive and often lethal class of natural, synthetic and semi-synthetic painkillers. Prescription opioids include brand-name medications like OxyContin, Opana, Subsys, Fentora and Duragesic, as well as generic drugs like oxycodone, methadone and fentanyl. In all, more than 200,000 people died in the United States between 1999 and 2016 from overdoses directly related to prescription opioids.[9] This number does not take into account the staggering number of additional illicit opioid deaths that can be related back to doctor-prescribed opioids; indeed, four out of five new heroin users began with prescription opioid misuse, which subsequently led to heroin use. Further, in 2018 it was determined that opioid related overdoses have likely been grossly underreported, possibly on the order of 70,000 deaths between 1999 and 2015.[10] The epidemic has become so severe that "[o]n an average day in 2016, 175 people died of an overdose, a rate of seven fatalities an hour."

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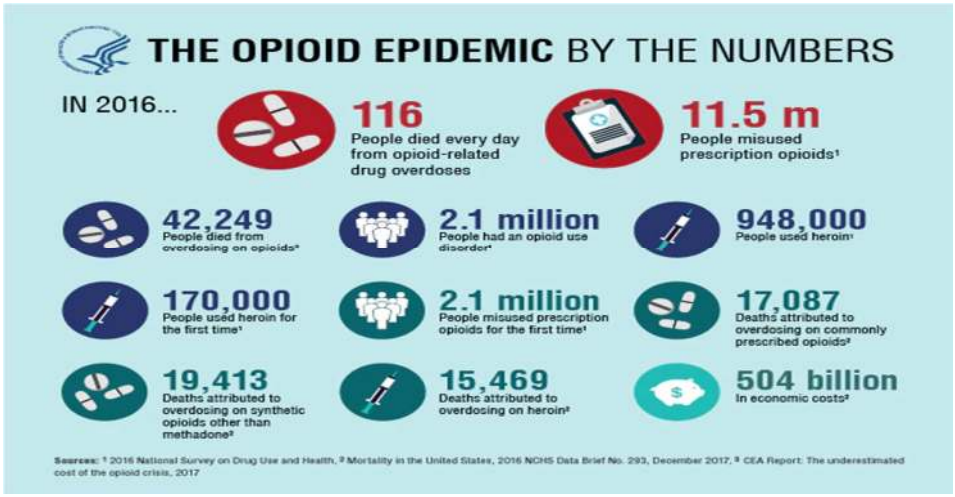
[8] *Opioid Overdose*, CDC (2017), available at https://www.cdc.gov/drugoverdose/data/index.html (last accessed June 8, 2018); Holly Hedegaard, Margaret Warner and Arialdi M. Miniño, *NCHS Data Brief No. 294: Drug Overdose Deaths in the United States, 1999-2016*, CDC (2017), available at https://www.cdc.gov/nchs/data/databriefs/db294.pdf (Last Accessed June 4, 2018).

[9] Christopher M. Jones, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers — United States, 2002-2004 and 2008-2010*, 132 (1-2) DRUG AND ALCOHOL DEPENDENCE 95-100 (2013), available at http://www.drugandalcoholdependence.com/article/S0376-8716(13)00019-7/fulltext (Last Accessed June 4, 2018).

[10] http://time.com/5323377/opioid-overdose-deaths-underreported/. (Last accessed July 29, 2018).



[11]

15. Further, according to Robert Anderson ("Anderson"), Chief of the Mortality Statistics Branch of the National Center for Health Statistics, deaths from synthetic opioids have undergone "more than an exponential increase," with an expected trend line for 2017 deaths that "will be at least as steep as 2016, if not steeper."[12] Between 2005 and 2016, fatal overdoses from synthetic opioids doubled. This surge in overdose deaths resulted in the first two-year drop in average United States life expectancy since the early 1960s.[13]

16. Defendants manufacture prescription opioids, including brand-name drugs like OxyContin and Percocet, and generic equivalents like oxycodone and hydrocodone, all of which are narcotic painkillers, pumped out to residents of San Mateo County.

17. In the late 1990s, opioid manufacturers began a sophisticated marketing scheme premised on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain. The manufacturers spent, and some continue to spend, millions of dollars on

[11] *Sessions unveils new task force targeting opioid manufacturers, distributors* DAILY NEWS (Feb. 28, 2018), available at https://www.studentnewsdaily.com/daily-news-article/sessions-unveils-new-task-force-targeting-opioid-manufacturers-distributors/ (Last Accessed June 13, 2018).

[12] Christopher Ingraham, *CDC releases grim new opioid overdose figures: 'We're talking about more than an exponential increase'*, WASH POST (Dec. 21, 2017), available at https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?noredirect=on&utm_term=.7bcf3b709d68 (Last Accessed June 4, 2018).

[13] Rob Stein, *Life Expectancy Drops Again As Opioid Deaths Surge In United States*, NPR (December 21, 2017), available at https://www.npr.org/sections/health-shots/2017/12/21/572080314/life-expectancy-drops-again-as-opioid-deaths-surge-in-u-s (Last Accessed June 4, 2018).

promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate their benefits. As to the risks, manufacturers falsely and misleadingly: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction," claiming that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction. Manufacturers also falsely touted the benefits of long-term opioid use, including its supposed ability to improve function and quality of life, even though there was no "good evidence" to support those benefits.

18. Unnamed co-conspirator distributors were aware of the misinformation being disseminated by the manufacturers and took active steps to assist the manufacturers. The Defendants knowingly supplied dangerous quantities of opioids while advocating for limited government oversight and enforcement. Defendants refused or failed to identify, investigate, or report suspicious orders of opioids to the authorities. Even when the Defendants had actual knowledge that the opioids were winding up in drug diversion rings, they refused or failed to report these sales.

19. By not reporting suspicious opioid orders or known diversions of prescription opioids, not only were the Defendants able to continue to sell opioids to questionable customers, but the Defendants also removed the basis for the DEA to either decrease or refuse increases to production quotas for prescription opioids.

20. The Defendant Manufacturers collaborated with each other and with unnamed co-conspirator opioid distributors to maintain distribution of excessive amounts of opioids.

21. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis, including in San Mateo County. The County and California face skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences stemming from these issues. This public health crisis is a public nuisance because it "is injurious to health" and interferes "with the comfortable enjoyment of life and property" (Civ. Code, § 3479) and because it affects "entire communit[ies]" and "neighborhood[s]" and "any

considerable number of persons" (Civ. Code, § 3480). The effects of each Defendant's distribution scheme are catastrophic and only getting worse.[14]

22. There is little doubt that each Defendant's actions has precipitated this public health crisis in California, including in San Mateo County, by dramatically increasing opioid prescriptions and use. An unchecked supply of prescription opioids has provided a source for the illicit use or sale of opioids, while the widespread use of opioids has created a population of patients who are physically and psychologically dependent on them. When those patients can no longer afford or legitimately obtain opioids, they often turn to street-level dealers to buy prescription opioids or even heroin to satisfy their needs, resulting in detriments to both health (including through the potential ingestion of impure stock) and law enforcement (through crime related to street-level drug dealers and attempts to obtain illegal drugs).

23. Absent each Defendant's willingness to pump billions of opioid pills into the public, opioid prescribing, use, misuse, abuse, and addiction, would not have become so widespread, and the opioid epidemic that now exists would have been averted or, at the very least, much less severe.

24. "No area of the United States is exempt from this epidemic—we all know a friend, family member, or loved one devastated by opioids," said CDC Principal Deputy Director Anne Schuchat, M.D.

25. Defendants have created or assisted in the creation of a public nuisance.[15] Every act of malfeasance committed by each Defendant since the late 1990s subjects such Defendant to liability for public nuisance because there is no statute of limitations for a public nuisance claim. (*See* Civ. Code, § 3490 ["No lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right"]; *Wade v. Campbell,* 200 Cal.App.2d 54, 61 (1962) ["the maintenance of a public nuisance may not be defended on the ground of laches or the statute of limitations"].)

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[14] *Califf, FDA top officials call for sweeping review of agency opioids policies,* FDA News Release (Feb. 4, 2016), available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.

[15] *See County of Santa Clara v. Atlantic Richfield Co.* 137 Cal.App.4th 292, 306 (2006) [holding that plaintiffs "have adequately alleged that defendants are liable for the abatement of this public nuisance" by alleging that defendants "promot[ed] lead paint for interior use even though defendants knew for nearly a century that such a use of lead paint was hazardous to human beings"].

26. Defendants' conduct, both individually and collectively, has violated and continues to violate the Public Nuisance Law, Civ. Code, §§ 3479 and 3480, the Unfair Competition Law, Bus. & Prof. Code, §§ 17200 *et seq*., and the False Advertising Law, Bus. & Prof. Code, §§ 17500 *et seq*.

27. This Court has personal jurisdiction over all of the Defendants by virtue of their business activities in this jurisdiction. All of the Defendants conduct substantial business within the State of California and the County of San Mateo.

28. San Mateo County continues to suffer significant financial consequences as a result of opioid over-prescription and addiction, including, but not limited to, increased law enforcement and judicial expenditures, increased jail expenditures, increased substance abuse treatment and diversion plan expenditures, increased emergency and medical care services, increased health insurance costs and lost economic opportunity.

II. PARTIES

A. PLAINTIFF

29. Plaintiff County of San Mateo ("the County") is a county and a political subdivision of the State of California. San Mateo is the 14th most populous county in California, with a population of more than 770,000 residents. San Mateo is home to several significant venues in Northern California, including the San Mateo County Expo Center, the South San Francisco Expo Center, the Cow Palace, and numerous Silicon Valley companies.

30. Plaintiff brings this action to recover damages and to protect the residents of San Mateo County from a public nuisance, and unlawful, unfair, and fraudulent business practices.

31. Plaintiff, acting by and through John C. Beiers, County Counsel for the County of San Mateo, is authorized to bring the causes of action brought herein. The County is a body corporate and politic of the State of California Cal. Gov't Code § 23003 and is authorized to bring this action. Cal. Gov't Code § 23004(a).

32. The County of San Mateo has responsibility for the public health, safety and welfare of its citizens.

33. Opioid abuse, addiction, morbidity and mortality have created a serious public health and safety crisis, which is a public nuisance, in San Mateo County. Further, the diversion of legally produced controlled substances into the illicit market contributes to this public nuisance.

34. The distribution and diversion of opioids into California, and into San Mateo County and surrounding areas, created the foreseeable opioid epidemic and opioid public nuisance for which Plaintiff seeks relief.

35. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation and (6) costs associated with the County having to repair and remake its infrastructure, property and systems that have been damaged by Defendants' actions, including, *inter alia*, its property and systems to treat addiction and abuse, to respond to and manage an elevated level of crime, to treat injuries, and to investigate and process deaths in San Mateo County. These damages have been suffered, and continue to be suffered, directly by the County.

36. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

37. Plaintiff has standing to bring an action for the opioid epidemic nuisance created by Defendants. Cal. Civ. Proc. Code § 731 ("A civil action may be brought in the name of the people of the State of California to abate a public nuisance, as defined in Section 3480 of the Civil Code, by the . . . county counsel of any county in which the nuisance exists.").

38. The County has standing to bring an action for damages incurred to its property by the public nuisance created by Defendants. Cal. Civ. Proc. Code § 731 ("An action may be brought

by any person whose property is injuriously affected, . . . and by the judgment in that action the nuisance may be enjoined or abated as well as damages recovered therefor.").

39. The County has standing to recover damages incurred as a result of Defendants' actions and omissions. Cal. Gov't Code § 23004(a).

B. DEFENDANTS

40. Defendant **Purdue Pharma L.P**. is a Delaware limited partnership formed in 1991 with headquarters located in Stamford, Connecticut. The company maintains four operational branches: **Purdue Pharma L.P.**, the **Purdue Frederick Company**, and **Purdue Products L.P.** In addition, **Perdue Pharma Inc.** operates as a manufacturer of opioids. **Defendants Richard Sackler**, **Jonathan Sackler**, **Mortimer Sackler**, **Kathe Sackler**, **Ilene Sackler Lefcourt**, and **Beverly Sackler** have been members of the board of **Purdue Pharma Inc.** since the 1990s. **Defendant David Sackler** joined them in 2012. All led the deception at **Purdue Pharma Inc.** and **Purdue Pharma L.P.** (These entities and individuals will be referred to collectively herein as "**Purdue**".)

41. Defendant **Cephalon, Inc.** is a Delaware corporation with its headquarters and principal place of business located in Frazer, Pennsylvania. **Cephalon, Inc.** was acquired by defendant **Teva Pharmaceutical Industries Ltd.** ("**Teva Ltd.**") in October 2011. **Teva Ltd.** is incorporated under the laws of Israel with its principal place of business in Petah Tikva, Israel. Since **Teva Ltd.** acquired **Cephalon, Inc.**, its United States sales and marketing activities have been conducted by defendant **Teva Pharmaceuticals USA, Inc.** ("**Teva USA**" and, together with **Teva, Ltd.**, "**Teva**"), a wholly-owned operating subsidiary of **Teva Ltd. Teva USA**'s headquarters and principal place of business are in North Wales, Pennsylvania. **Cephalon, Inc.** and **Teva** are collectively referred to herein as "**Cephalon**."

42. Defendant **Endo International plc** is an Irish public limited company with its headquarters in Dublin, Ireland. Defendant **Endo Health Solutions Inc.** is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Defendant **Endo Pharmaceuticals Inc.** (together with **Endo International plc** and **Endo Health Solutions Inc.**, "**Endo**") is a Delaware corporation with its headquarters and principal place of business in Malvern,

Pennsylvania. **Endo Pharmaceuticals Inc.** is an indirectly wholly-owned subsidiary of **Endo International plc.**

43. Defendant **Janssen Pharmaceuticals, Inc.** (formerly known as **Ortho-McNeil-Janssen Pharmaceuticals, Inc.** and **Janssen Pharmaceutical**) is headquartered in Titusville, New Jersey and Raritan, New Jersey. Janssen is a wholly-owned subsidiary of **Johnson & Johnson**, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. **Johnson & Johnson** is the only company that owns more than 10% of **Janssen Pharmaceuticals, Inc.**'s stock, and it corresponds with the FDA regarding Janssen's products. Upon information and belief, Johnson & Johnson controls the sale and development of Janssen Pharmaceutical's drugs, and **Janssen Pharmaceuticals, Inc.**'s profits inure to Johnson & Johnson's benefit. (**Janssen Pharmaceuticals, Inc**., **Ortho-McNeil-Janssen Pharmaceuticals, Inc**., **Janssen Pharmaceutica, Inc**., and **Johnson & Johnson** collectively are referred to herein as "**Janssen**.")

44. Defendant **Insys Therapeutics, Inc.** ("**Insys**") is a Delaware corporation with its principal place of business in Chandler, Arizona.

45. Defendant **Mallinckrodt plc** is an Irish public limited company with its headquarters in Staines-upon-Thames, Surrey, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Defendant **Mallinckrodt LLC** (together with **Mallinckrodt Plc**, "**Mallinckrodt**") is a limited liability company organized under the laws of the State of Delaware and headquartered in St. Louis, Missouri. **Mallinckrodt LLC** is a wholly owned subsidiary of **Mallinckrodt Plc**.

46. **Allergan PLC** is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. **Actavis PLC** acquired **Allergan PLC** in March 2015, and the combined company changed its name to **Allergan PLC** in March 2015. Prior to that, **Watson Pharmaceuticals, Inc**. acquired **Actavis, Inc.** in October 2012; the combined company changed its name to **Actavis, Inc.** in January 2013 and then to **Actavis plc** in October 2013. **Watson Laboratories, Inc.** is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of **Allergan PLC** (f/k/a **Actavis, Inc**., f/k/a **Watson Pharmaceuticals, Inc**.). **Actavis Pharma, Inc**. (f/k/a **Actavis, Inc**.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as **Watson Pharma, Inc.**

Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by **Allergan plc**, which uses them to market and sell its drugs in the United States. Upon information and belief, **Allergan plc** exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (**Allergan plc**, **Actavis plc**, **Actavis, Inc.**, **Actavis LLC**, **Actavis Pharma, Inc.**, **Allergan Finance LLC**, **Watson Pharmaceuticals, Inc.**, **Watson Pharma, Inc.**, and **Watson Laboratories, Inc.** hereinafter collectively are referred to as "**Actavis**.")

C. AIDING, ABETTING AND CO-CONSPIRATORS

47. Known unnamed co-conspirators include the distributors of prescription opioids, including McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation, and numerous others.

III. JURISDICTION AND VENUE

48. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1332.

49. Venue is proper pursuant to 28 U.S.C. §1391. This Court has personal jurisdiction over each defendant as each purposefully availed itself of the privilege of exploiting forum-based business opportunities and the exercise of personal jurisdiction is consistent with Cal. Civ. Proc. § 410.10.

IV. GLOSSARY OF RELEVANT TERMS

50. Plaintiff includes the following glossary of relevant terms, as those terms are used in this Complaint:[16]

51. **Acute Pain**: Pain that usually starts suddenly and has a known cause, like an injury or surgery. It normally gets better as your body heals and lasts less than three months.

52. **Benzodiazepines**: Sometimes called "benzos," these are sedatives often used to treat anxiety, insomnia, and other conditions. Combining benzodiazepines with opioids increases a person's risk of overdose and death.

[16] Except as otherwise noted, the terms in this Section are defined in accordance with the definitions adopted by the CDC. *See Opioid Overdose: Commonly Used Terms*, CDC (2017), available at https://www.cdc.gov/drugoverdose/opioids/terms.html (Last Accessed June 4, 2018).

53. **Big Pharma**: large pharmaceutical companies, especially as a politically influential group.[17]

54. **Chronic pain**: Pain that lasts three (3) months or more and can be caused by a disease or condition, injury, medical treatment, inflammation, or even an unknown reason.

55. **Drug misuse**: The use of prescription drugs without a prescription or in a manner other than as directed by a doctor, including use without a prescription of one's own; use in greater amounts, more often, or longer than told to take a drug; or use in any other way not directed by a doctor.

56. **Drug abuse or addiction**: Dependence on a legal or illegal drug or medication. *See* Opioid use disorder.

57. **Extended-release/long-acting (ER/LA) opioids**: Slower-acting medication with a longer duration of pain-relieving action.

58. **Fentanyl**: Pharmaceutical fentanyl is a synthetic opioid pain medication, approved for treating severe pain, typically advanced cancer pain. It is 50 to 100 times more potent than morphine. However, illegally made fentanyl is sold through illegal drug markets for its heroin-like effect, and it is often mixed with illegal drugs such as heroin and/or cocaine as a combination product.

59. **Heroin**: An illegal, highly addictive opioid drug processed from morphine.

60. **Illicit drugs**: The non-medical use of a variety of drugs that are prohibited by law.

These drugs can include: amphetamine-type stimulants, cocaine, heroin and other opioids, synthetic drugs, and MDMA (ecstasy).

61. **Immediate-release opioids**: Faster-acting medication with a shorter duration of pain-relieving action.

62. **Key-Opinion Leader ("KOL")**: A phrase used by marketing departments of pharmaceutical companies for especially influential physicians they seek to influence.[18]

[17] *Definition of Big Pharma*, WEBSTER (2018), available at https://www.merriam-webster.com/dictionary/Big%20Pharma (Last Accessed June 4, 2018).

[18] Sergio Sismondo, PhD, *How to make opinion leaders and influence people,* 187 (10) CMAJ 759-760 (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4500705/ (Last Accessed June 4, 2018); *see also Fueling an Epidemic: Report Two*, HSGAC (2018), available at

63. **Naloxone**: A prescription drug that can reverse the effects of opioid overdose and can be life-saving if administered in time. The drug is sold under the brand name Narcan or Evzio.

64. **Narcotic:** Also known as "opioids," the term "narcotic" comes from the Greek word for "stupor" and originally referred to a variety of substances that dulled the senses and relieved pain. Though some people still refer to all drugs as "narcotics," today "narcotic" refers to opium, opium derivatives, and their semi-synthetic substitutes.[19] A more current term for these drugs, with less uncertainty regarding its meaning, is "opioid." Examples include the illicit drug heroin and pharmaceutical drugs like OxyContin®, Vicodin®, codeine, morphine, methadone, and fentanyl.

65. **Nonmedical use**: Taking drugs, whether obtained by prescription or otherwise, not in the way, for the reasons, or during the time period prescribed, or the use of prescription drugs by a person for whom the drug was not prescribed.

66. **Non-opioid therapy**: Methods of managing chronic pain that do not involve opioids. These methods can include, but are not limited to, acetaminophen (Tylenol®) or ibuprofen (Advil®), cognitive behavioral therapy, physical therapy and exercise, medications for depression or for seizures, or interventional therapies (including injections).

67. **Opioid**: Natural or synthetic chemicals that interact with opioid receptors on nerve cells in the body and brain and reduce the intensity of pain signals and feelings of pain. This class of drugs includes the illegal drug heroin, synthetic opioids such as fentanyl, and pain medications available legally by prescription, such as oxycodone, hydrocodone, codeine, morphine, and many others. Opioid pain medications are generally safe when taken for a short time and as prescribed by a doctor, but because they produce euphoria in addition to pain relief, they can be, and too often are, misused. *See also*, "Narcotic." Advocates of aggressive pain-treatment coined the term "opioid" to rebrand drugs that would otherwise be labelled "narcotics."

68. **Opioid agonist/Opioid antagonist**: An "agonist" medication is one that binds to and fully activates targeted receptors in the brain. They activate these neurotransmitter receptors to illicit

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https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (Last Accessed June 4, 2018).

[19] *Drug Fact Sheet*, DEA, available at https://www.dea.gov/druginfo/drug_data_sheets/Narcotics.pdf (Last Accessed June 13, 2018).

a certain response. An "antagonist" medication, on the other hand, works to prevent the binding of other chemicals to neurotransmitters in order to block a certain response. Both may be used to offer pain relief.[20]

69. **Opioid analgesics**: Commonly referred to as prescription opioids, medications that have been used to treat moderate to severe pain in some patients. Categories of opioids for mortality data include:

- Natural opioid analgesics, including morphine and codeine;
- Semi-synthetic opioid analgesics, including drugs such as oxycodone, hydrocodone, hydromorphone, and oxymorphone;
- Methadone, a synthetic opioid; and
- Synthetic opioid analgesics other than methadone, including drugs such as tramadol and fentanyl.

70. **Opioid use disorder**: A problematic pattern of opioid use that causes significant impairment or distress. A diagnosis is based on specific criteria, such as unsuccessful efforts to cut down or control use, or use resulting in social problems and a failure to fulfill obligations at work, school, or home. Opioid use disorder has also been referred to as "opioid abuse or dependence" or "opioid addiction."

71. **Opiophobia**: A term coined by Big Pharma as a derogative term describing doctors who were too conservative in treating pain and prescribing opioids.[21]

72. **Overdose**: Injury to the body (poisoning) that happens when a drug is taken in excessive amounts. An overdose can be fatal or nonfatal.

73. **Physical dependence**: Adaptation to a drug that produces symptoms of withdrawal within an individual when use of that drug is stopped.

[20] *What is the Difference Between Agonist and Antagonist Drugs*, REFERENCE (2018), available at https://www.reference.com/health/difference-between-agonist-antagonist-drugs-838e9e0994a788eb# (Last Accessed June 4, 2018).

[21] Eric Levitz, *Purdue Pharma Knew Its Opioids Were Widely Abused by Late '90s*, NY MAG (May 29, 2018), available at http://nymag.com/daily/intelligencer/2018/05/purdue-knew-its-opioids-were-widely-abused-by-late-90s.html (Last Accessed June 4, 2018).

74. **Prescription drug monitoring programs (PDMPs)**: State-run electronic databases that track controlled substance prescriptions. PDMPs help providers identify patients at risk of opioid misuse, abuse and/or overdose due to overlapping prescriptions, high dosages, or the co-prescription of opioids with benzodiazepines. In California, CURES 2.0 (Controlled Substance Utilization Review and Evaluation System), maintained by the U.S. Department of Justice, is a database of Schedule II, III and IV controlled substance prescriptions dispensed in California, serving public health and regulatory oversight agencies, and law enforcement.

75. **Pseudoaddiction**: Pseudoaddiction, a concept coined in 1989, has frequently been cited to indicate that under-treatment of pain, rather than addiction, is the more pressing and authentic clinical problem in opioid-seeking patients. Industry sponsored publications argued that pseudoaddiction is a condition resulting from withholding opioids for pain that can be diagnosed, prevented, and treated with *more aggressive* opioid treatment.[22]

76. **Tolerance**: Reduced response to a drug due to repeated use.

V. FACTUAL ALLEGATIONS

77. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

78. To take advantage of the much larger and more lucrative market for chronic pain patients, opioid manufacturers had to change this. Manufacturers developed a well-funded marketing scheme to target susceptible prescribers and vulnerable patient populations. Manufacturers funded seemingly independent third-parties (and used their own sales forces) to spread false and misleading statements about the risks and benefits of long-term opioid use. These statements were not only

[22] Marion S. Greene and R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2(4) CURRENT ADDICT REP. 310-317 (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4628053/ (Last Accessed June 4, 2018).

unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the U.S. Food and Drug Administration ("FDA") and CDC based on that same evidence. California doctors, including doctors in San Mateo County, confirm that Defendants began their marketing schemes decades ago and continue them today.

A. MANUFACTURERS TARGETED SUSCEPTIBLE PRESCRIBERS AND VULNERABLE PATIENT POPULATIONS

79. From the mid-90s to the present, the Defendants aggressively marketed and falsely promoted liberal opioid prescribing as presenting little to no risk of addiction, even when used long-term for chronic pain. They infiltrated academic medicine and regulatory agencies to convince doctors that treating chronic pain with long-term opioids was evidence-based medicine when, in fact, it was not. Huge profits resulted from these efforts, as did the present addiction and overdose crisis.

80. The Defendants' scheme to drive their rapid and dramatic expansion of prescription opioids was rooted in two pieces of so-called evidence: First was the publication of a 100-word letter to the editor published in 1980 in the New England Journal of Medicine ("1980 Letter to the Editor").[23] A recent article about the 1980 Letter to the Editor, titled "A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever," quoted a 2017 study in the New England Journal of Medicine, in which researchers concluded:

> [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.[24]

[23] Jane Porter & Hershel Jick, *Addiction rare in patients treated with narcotics*, 302(2) N ENGL J MED. 123 (1980); Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER (May 26, 2016), available at http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5 (Last Accessed June 4, 2018).

[24] German Lopez, *A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever*, VOX (June 1, 2017), available at https://www.vox.com/science-and-health/2017/6/1/15723034/opioid-epidemic-letter-1980-study (Last Accessed June 4, 2018).

81. Second was a medical study published by Drs. Russell Portenoy ("Portenoy") and Kathleen Foley ("Foley") ("Portenoy Publication").[25] In 1986, the medical journal Pain (later to become the official journal of the American Pain Society ("APS")), published an article by Portenoy and Foley summarizing the results of a so-called study of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." This study, which was a pivotal factor in the proliferation of opioids, did not meet the rigorous standards needed for research in the medical community. There was no placebo control group and the results were retroactive (i.e., examiners asked patients to describe prior experiences with opioids). The authors themselves advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer-term studies of patients on opioids would have to be performed. None were. Portenoy emerged as one of the industry's most vocal proponents of long-term opioid use, and essentially made it his life's work to campaign for the movement to increase use of prescription opioids – Portenoy referred to opioids as a "gift from nature."[26] He was one of Big Pharma's "thought leaders" and was paid to travel the country to promote more liberal opioid prescribing for pain. His talks were sponsored by the Defendants and organizations paid by them as CME programs for doctors. He had financial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids.[27]

82. On November 1, 2017, the President's Commission on Combating Drug Addiction and the Opioid Epidemic noted the important and detrimental role played by the 1980 Letter to the Editor and the Portenoy Publication. In a section of the Commission's Report with the header "Contributors to the Current Crisis," the Commission wrote the following:

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

[26] Patrick Radden Keefe, *The Family That built An empire Of Pain*, THE NEW YORKER (Oct. 30, 2017), available at https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain (Last Accessed June 4, 2018).

[27] Lembke, *Drug Dealer*, *supra n.* 10 at 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (St. Martin's Press, 1st ed. 2003)).

> Unsubstantiated claims: One early catalyst can be traced to a single letter to the Editor of the New England Journal of Medicine published in 1980, that was then cited by over 600 subsequent articles. With the headline "Addiction Rare in Patients Treated with Narcotics," the flawed conclusion of the five-sentence letter was based on scrutiny of records of hospitalized patients administered an opioid. It offered no information on opioid dose, number of doses, the duration of opioid treatment, whether opioids were consumed after hospital discharge, or long-term follow-up, nor a description of criteria used to designate opioid addiction. Six years later, another problematic study concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse." High quality evidence demonstrating that opioids can be used safely for chronic non-terminal pain did not exist at that time. These reports eroded the historical evidence (see Appendix 2) of iatrogenic addiction and aversion to opioids, with the poor-quality evidence that was unfortunately accepted by federal agencies and other oversight organizations.[28]

83. Portenoy has now admitted that he minimized the risks of opioids. 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.[29]

84. The damage, however, was already done. The Defendants used these two publications, the 1980 Letter to the Editor and the Portenoy Publication, as the foundation for a massive, far-reaching campaign to dramatically shift the thinking of healthcare providers, patients, policymakers and the public on the risk of addiction presented by opioid therapy. By 1997, the APS and the American Academy of Pain Medicine ("AAPM") (both funded by the Defendants) issued a "landmark consensus," co-authored by Portenoy, stating there is little risk of overdose or addiction in pain patients.

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[28] *The President's Commission on Combating Drug Addiction and the Opioid Crisis*, at 20 (2017), available at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf (Last Accessed June 4, 2018).

[29] Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YOUTUBE (2011), available at https://www.youtube.com/watch?v=DgyuBWN9D4w (Last Accessed June 4, 2018).

85. In the years following publication of the 1980 Letter to the Editor and the Portenoy Publication, Defendants introduced powerful prescription opioids into the market. Purdue introduced MS Contin in 1987 and OxyContin in 1995, Janssen introduced Duragesic in 1990 and Cephalon's Actiq was first approved by the FDA in 1998. More recently, Endo's Opana and Opana ER were approved by the FDA in 2006, as was Janssen's Nucynta in 2008 and Nucynta ER in 2011, Cephalon's Fentora in 2006 and Insys' Subsys in 2012.

86. These branded prescription opioids and their generic counterparts are highly addictive. Between doses, patients can suffer body aches, nausea, sweats, racing heart, hypertension, insomnia, anxiety, agitation, opioid cravings, opioid-induced hyperalgesia (heightened sensitivity to pain) and other symptoms of withdrawal. When the agony is relieved by the next dose, it creates a cycle of dysphoria and euphoria that fosters addiction and dependence.

87. Despite the prescription opioids' highly addictive qualities, the Defendants launched aggressive pro-opioid marketing efforts that caused a dramatic shift in the public's and prescribers' perception of the safety and efficacy of opioids for chronic long-term pain and everyday use. Defendants falsely claimed that: (i) the risk of becoming addicted to prescription opioids among patients being treated for pain was low, even as low as less than 1%; and (ii) great harm was caused by "under-treated pain." These two falsehoods underpin the current opioid epidemic.

88. As a part of their deceptive marketing scheme, manufacturers identified and targeted susceptible prescribers and vulnerable patient populations in the United States, including in California.

89. For example, manufacturers focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs but were less likely to be schooled in treating pain and the comparative risks and benefits of opioids, and therefore more likely to accept manufacturers' misrepresentations.

90. Manufacturers also targeted vulnerable patient populations like the elderly and veterans, who are more likely than the average member of the population to suffer from chronic pain. This targeting occurred even though the medical risks and injury potential of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observed that existing

evidence showed that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concluded that there are "special risks of long-term opioid use for elderly patients" and recommended that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines), which interact dangerously with opioids, for post-traumatic stress disorder.

91. Big Pharma's strategy was a brilliant marketing success. It was designed to label back pain, neck pain, headaches, arthritis, fibromyalgia and other common conditions suffered by most of the population at some point in their lives as a distinct malady — chronic pain — that doctors and patients should take seriously and for which opioids were an appropriate, successful and low-risk treatment.[30] Indeed, studies now show more than 85% of patients taking OxyContin at common doses are doing so for chronic non-cancer pain."[31]

92. Defendants' false and misleading marketing strategy continued despite studies revealing that up to 56% of patients receiving long-term prescription opioid painkillers for chronic back pain progress to addictive opioid use, including patients with no prior history of addiction.[32]

93. Defendants' representations to the contrary, there was no reliable, scientifically sound evidence of opioids' efficacy for the treatment of chronic pain. In fact, 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 JAMA.[33] The trial, sponsored by the U.S. Department of Veterans Affairs ("Veterans Affairs"), was a randomized, 12-month study of 240

[30] Sonia Moghe, *Opioid History: From 'wonder drug' to abuse epidemic*, CNN (Oct. 14, 2019), available at https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html (Last Accessed June 4, 2018).

[31] Harriet Ryan, Lisa Girion and Scott Glover, *OxyContin goes global – "We're only just getting started"*, LA TIMES (Dec. 18, 2016), available at http://www.latimes.com/projects/la-me-oxycontin-part3/ (Last Accessed June 4, 2018).

[32] Lembke (2016), *supra n*. 10 at 22 (citing BA Martell, *et al.*, *Ststematic review: opioid treatment for chronic back pain: prevalence, efficacy, and association with addiction*, 146(2) ANN INTERN MED. 116-27 (2007)).

[33] EE Krebs, *et al.*, *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial,* 319 (9) JAMA 872-882 (Mar 2018).

patients at Veterans Affairs' primary care clinics. Each of the eligible patients had moderate to severe chronic back pain or hip or knee osteoarthritis despite the use of analgesic drugs.

94. The researchers reported that "There 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 other non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen. As such, they concluded: "Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."

95. Defendants used false and incomplete evidence to expand their market from patients with end-stage cancer and acute pain to anyone suffering from chronic pain, which by some accounts includes approximately 100 million Americans—nearly one-third of the country's population. The treatment of chronic pain includes patients whose general health is good enough to refill prescriptions month after month, year after year, and the promotion, distribution (without reporting suspicious sales) and rampant sale of opioids for such treatment has made Defendants billions of dollars. It has also led to the prevalence of opioid addiction and overdose in San Mateo County.

B. THE FRAUDULENT SALES PRACTICES

96. The Defendants employed a variety of strategies to encourage the use of opioids for chronic long-term pain without informing the public and prescribers about the very significant risk of addiction, overdose and death.

97. In order to change the mindset of prescribers, Defendants funded front groups that had the appearance of independent medical organizations (including medical boards and foundations), speakers' bureaus (with speakers that again had the appearance of independence) and individual doctors (so called "thought leaders.") All these avenues simply provided methods for disseminating the Manufacturer Defendants' message that opioids are safe, could be used in a broad range of patients and had little risk of addiction, even when used long-term.[34]

[34] Evan Hughes, *The Pain Hustlers*, N.Y. TIMES MAG (May 2, 2018), available at https://www.nytimes.com/interactive/2018/05/02/magazine/money-issue-insys-opioids-kickbacks.html (Last Accessed June 4, 2018).

98. The following organizations were among those that the Manufacturer Defendants fronted:

99. **Federation of State Medical Boards**: The Federation of State Medical Boards ("FSMB") is a national organization that functions as a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice.[35] Defendants Purdue, Cephalon and Endo have provided substantial funding to the FSMB. Among its members are the **Medical Board of California** and the **Osteopathic Medical Board of California**.

100. In 2007, the FSMB printed and distributed a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing" by Dr. Scott M. Fishman ("Fishman").[36] After the guide (in the form of a book, still available for sale on Amazon) was adopted as a model policy, the FSMB reportedly asked Purdue for $100,000 to help pay for printing and distribution.[37] Ultimately, the guide was circulated by the FSMB to 700,000 practicing doctors. *Id.* The guide's clear purpose is to focus prescribers on the purported under-treatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain:

- Pain management is integral to good medical practice and for all patients;
- 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;
- Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

* * *

Four key factors contribute to the ongoing problem of under-treated pain:

[35] *About FSMB*, FSMB (2018), available at https://www.fsmb.org/about-fsmb/fsmb-leadership/ (Last Accessed June 4, 2018).
[36] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, (Waterford Life Sciences 2007), archive available at https://archive.org/stream/279187-responsible-opioid-prescribing-info/279187-responsible-opioid-prescribing-info_djvu.txt (Last Accessed June 5, 2018).
[37] John Fauber, *Follow the Money: Pain, Policy, and Profit*, MEDPAGE (Feb. 19, 2012), available at https://www.medpagetoday.com/neurology/painmanagement/31256 (Last Accessed June 4, 2018).

1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;
2. The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities;
3. Misunderstanding of addiction and dependence; and
4. Lack of understanding of regulatory policies and processes.

101. While it acknowledges the risk of "abuse and diversion" (with little attention to addiction), the guide purports to offer "professional guidelines" that will "easily and efficiently" allow physicians to manage the risks and "minimize the potential for [such] abuse."' Indeed, the guide states that even for those patients assessed to have risk of substance abuse, "it does not mean that opioid use will become problematic or that opioids are contraindicated," just that physicians should use additional care in prescribing.

102. The guide further warns physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and teaches that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids," which are, in fact, signs of genuine addiction, are all really just signs of "pseudoaddiction." It defines "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction and states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence. The guide, sponsored by the Manufacturer Defendants and their pain foundations, became the seminal authority on opioid prescribing for the medical profession and dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

103. In 2012, 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.

104. The updated guide still assures that "opioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."

105. In another guide by 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.*"[38] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

106. The heightened focus on the under-treatment of pain was a concept designed by Big Pharma to sell opioids. The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain.[39] Among the drafters of this policy was Dr. J. David Haddox ("Haddox"), who coined the term "pseudoaddiction," which wholly lacked scientific evidence but quickly became a common way for the Manufacturer Defendants and their allies to promote the use of opioids, even to patients displaying addiction symptoms. Haddox later became a Purdue vice president who likened OxyContin to a vegetable, stating at a 2003 conference at Columbia University: "If I gave you a stalk of celery and you ate that, it would be healthy. But if you put it in a blender and tried to shoot it into your veins, it would not be good."

107. As will be described in more detail, in 2012 and again in 2017, the guides and the sources of their funding became the subject of a Senate investigation.

108. On June 8, 2012, the FSMB submitted a letter to the U.S. Senate Finance Committee concerning its investigation into the abuse and misuse of opioids.[40] While the letter acknowledged the escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain — a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated, "[s]tudies have concluded that both acute pain and chronic pain are

[38] Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* at 45 (Oxford University Press 2012).
[39] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J. (Dec. 17, 2012), at Al.
[40] Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley (Jun. 8, 2012).

often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." The letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" has been distributed in each of the 50 states and the District of Columbia.

109. In addition, the FSMB letter disclosed payments the FSMB received from organizations that develop, manufacture, produce, market or promote the use of opioid-based drugs from 1997 through 2012. Included in the payments received were payments from Defendants Purdue, Endo, Cephalon, and Mallinckrodt. The letter also disclosed payments of $40,000 by Endo and $50,000 by Purdue to directly fund the production of "Responsible Opioid Prescribing" and disclosed that sales of "Responsible Opioid Prescribing" generated more than $2.75 million in revenues from sales in California.

110. **The Joint Commission**: The Joint Commission is an organization that establishes standards for treatment and accredits healthcare organizations in the United States.[41] The Manufacturer Defendants, including Purdue, contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what Big Pharma coined the "under-treatment of pain," referenced pain as the "fifth vital sign" (the first and only unmeasurable/subjective vital sign) that must be monitored and treated, and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. In a 1999 report the Joint Commission called doctors' concerns about addiction "inaccurate and exaggerated."[42]

111. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies claiming "there is no evidence that addiction is a significant issue when persons are given opioids for pain control." The book was sponsored by Purdue.

[41] *About the Joint Commission*, THE JOINT COMMISSION (2018), available at https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx (Last Accessed June 4, 2018).

[42] Jeremy Samuel Faust, *The Untold Story of America's Opioid Addiction*, SLATE (June 3, 2016), available at http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html (Last Accessed June 4, 2018).

112. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies) collaborated to issue a 101-page monograph titled "Pain: Current understanding of assessment, management, and treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous":

> Societal issues that contribute to the under treatment of pain include drug abuse programs and erroneous beliefs about tolerance, physical dependence, and addiction (see I.E.5). For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction.
>
> a. Etiology, issues, and concerns
> Many medications produce tolerance and physical dependence, and some (e.g., opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction in vulnerable individuals. Most experts agree that patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders. In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low. A recent study of opioid analgesic use revealed "low and stable" abuse of opioids between 1990 and 1996 despite significant increases in opioids prescribed.
> . . .
> Fear of causing addiction (Le. iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management this fear sometimes reflects a lack of understanding of the risk of addiction with therapeutic drug use. Although studies suggest that the risk of iatrogenic addiction is quite low (e.g., Perry and Heidrich, Zenz et al.), surveys indicate that clinicians often overestimate this risk.

113. Additionally, the monograph recommends that "[p]ain is assessed in all patients" and suggests that long-acting (i.e., extended release) pain medications are superior and should be used whenever possible:

> Long-acting and sustained-release opioids are useful for patients with continuous pain, as they lessen the severity of end-of-dose pain and often allow the patient to sleep through the night.
>
> Administer opioids primarily via oral or transdermal routes, using long-acting medications when possible.

114. In truth, such medications often do not last as long as promised, and there is evidence to suggest that the use of long-acting drugs may actually create more addicts.

115. Also in 2001 the Joint Commission began heavily promoting the now familiar 0-10

pain scale and began judging hospitals based on patient satisfaction with pain treatment.[43]

116. The Defendants' infiltration and influence over the Joint Commission's standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines. Consistent with the guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.

117. The U.S. General Accounting Office's December 2003 Report to Congressional Requesters entitled "OxyContin Abuse and Diversion and Efforts to Address the Problem" states the following regarding "What the GAO found" about Purdue and OxyContin:

> Purdue conducted an extensive campaign to market and promote OxyContin using an expanded sales force to encourage physicians, including primary care specialists, to prescribe OxyContin not only for cancer pain but also as an initial opioid treatment for moderate-to-severe noncancer pain. OxyContin prescriptions, particularly those for noncancer pain, grew rapidly, and by 2003 nearly half of all OxyContin prescribers were primary care physicians. The Drug Enforcement Administration (DEA) has expressed concern that Purdue's aggressive marketing of OxyContin focused on promoting the drug to treat a wide range of conditions to physicians who may not have been adequately trained in pain management. FDA has taken two actions against Purdue for OxyContin advertising violations. Further, Purdue did not submit an OxyContin promotional video for FDA review upon its initial use in 1998, as required by FDA regulations.[44]

The GAO report found that Purdue helped fund a "pain-management educational program" organized by the Joint Commission and that a related agreement allowed Purdue to disseminate educational materials on pain management, and this, in the words of the report, "may have facilitated its access to hospitals to promote OxyContin."

118. **The American Pain Foundation:** The American Pain Foundation ("APF") described itself as the nation's largest organization for pain patients. 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

[43] Julia Lurie, *A Brief, Blood-Boiling History of the Opioid Epidemic*, MOTHER JONES (Feb. 2017), available at https://www.motherjones.com/crime-justice/2017/12/a-brief-blood-boiling-history-of-the-opioid-epidemic/ (Last Accessed June 4, 2018).

[44] U.S. General Accounting Office, GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), available at http://www.gao.gov/new.items/d04110.pdf (Last Accessed June 4, 2018).

industry, including from Defendants Purdue, Endo, Janssen and Cephalon. It received more than $10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down days after the U.S. Senate Committee on Finance ("Senate Finance Committee") launched an investigation of APF's promotion of prescription opioids.[45]

119. The APF's guides for patients, journalists and policymakers trivialized the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers.

120. For example, in 2001, APF published "Treatment Options: A Guide for People Living with Pain."[46] The guide, which was produced due to support from companies including defendants Cephalon and Purdue, misrepresented the risks associated with opioid use. Among other things, the guide.

- lamented that opioids were sometimes called narcotics because ***"calling opioid analgesics 'narcotics' reinforces myths and misunderstandings*** as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines";
- stated that "[o]pioids are an essential option for treating ***moderate*** to severe pain associated with surgery or trauma"; " and
- opined that "[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction."

The guide included blurbs from Portenoy, who is quoted as saying "[t]his is a very good resource for the pain patient," and Fishman, who is quoted as saying, "[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A 'must have' for every physician's waiting room."

121. In 2003, APF published a newsletter titled "Best of . . . The Pain Community News" that purported to clarify any confusion over addiction and opioids and emphasized the "tragic consequence of

[45] Charles Ornstein and Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, PROPUBLICA (May 8, 2012), available at https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups (Last Accessed June 4, 2018); Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, PROPUBLICA (Dec. 23, 2011), available at https://www.propublica.org/article/the-champion-of-painkillers (Last Accessed June 4, 2018).

[46] *Treatment Options: A Guide for People Living with Pain*, AMERICAN PAIN FOUNDATION, available at https://ce4less.com/Tests/Materials/E019Materials.pdf (Last Accessed June 4, 2018).

leaving many people with severe pain under-treated because they — or their doctors —fear that opioids will cause addiction."

122. In 2009, Endo sponsored APF's publication and distribution of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families" ("Exit Wounds"), a book described as "the inspirational story of how one courageous veteran, with the aid of his family, recovered and thrived despite near death, traumatic brain injury, and the loss of a limb." It also purported to "offer[] veterans and their families comprehensive and authoritative information on . . . treatment options, and strategies for self-advocating for optimal pain care and medical resources inside and outside the VA system."

123. Among other false statements, Exit Wounds reported: "Long experience with opioids shows that ***people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."*** Endo, through APF, thus distributed false information with the purpose of providing veterans false information they could use to "self-advocat[e]" for opioids while omitting a discussion of the risks associated with opioid use.

124. In 2009, APF played a central role in a first-of-its-kind web-based series called "Let's Talk Pain," hosted by veteran TV journalist Carol Martin. The series brought together healthcare providers and "people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain. "The "Let's Talk Pain" talk show is still available online. In the very first episode of this talk show, the following exchange took place.

> [Teresa Shaffer (APF Action Network Leader):] As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a bit about that?
>
> [Dr. Al Anderson (AAPM Board of Directors):] The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor *when they are suffering from pain for a long period of time,* especially *moderate* to severe pain. And *that's the patients that we really need to use the opioids* methods of treatment, because they are the ones who need to have some help with the function and they're the ones that need to be controlled enough so that they can increase their quality of life.[47]

[47] *Episode 1: Safe Use of Opioids (PainSAFE)*, LET'S TALK PAIN (Sept. 28, 2010), available at https://www.youtube.com/watch?v=zeAlVAMRgsk (Last Accessed June 4, 2018).

125. In reality, there is little scientific evidence to support the contention that opioids taken long-term improve function or quality of life for chronic pain patients.[48] To the contrary, there is ample evidence that opioids impose significant risks and adverse outcomes on long-term users and may actually reduce function.[49] As a recent article in the *New England Journal of Medicine* concluded: "Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits of opioids when prescribed for chronic pain are much more questionable." The article continues, "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."[50] More recent still, a study published in *JAMA* concluded that "[t]reatment with opioids was *not* superior to treatment with nonopioid medications for improving pain-related function over 12 months."

126. The APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website called www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org promised that, on 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." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. In a brochure available on painknowledge.org titled "Pain: Opioid Facts," the NIPC misleadingly stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted" and even refused to rule out the use of opioid pain relievers for patients who have a history of addiction to opioids.[51]

[48] Roger Chou, M.D., *et al.*, *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, AHRQ (2014), available at https://www.ncbi.nlm.nih.gov/books/NBK258809/pdf/Bookshelf_NBK258809.pdf (Last Accessed June 5, 2018).

[49] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief— The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-04 (Apr. 21, 2016), available at https://www.nejm.org/doi/full/10.1056/NEJMp1515917 (Last Accessed June 4, 2018).

[50] Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies*, 374 New Eng. J. Med. 1253-63 (Mar. 31, 2016), available at https://www.nejm.org/doi/full/10.1056/nejmra1507771 (Last Accessed May 5, 2018).

[51] *Pain - Opioid Facts*, PAIN KNOWLEDGE (2007), archive available at http://web.archive.org/web/20070520130121/http://www.painknowledge.org:80/ (last visited June 9, 2018).

127. In or around 2011, the APF published the "Policymaker's Guide," sponsored by Purdue, which dispelled the notion that "strong pain medication leads to addiction" by characterizing it as a *"common misconception[]."*

> *Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive.* As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.

128. The guide describes "pain in America" as "an evolving public health crisis" and characterizes concerns about opioid addiction as misconceptions: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include: . . . ***Misconceptions about opioid addiction."*** It even characterizes as a ***"myth"*** that ***"[c]hildren can easily become addicted to pain medications."*** The guide further asserts 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, which was not the case.[52]

129. In December 2011, the ***Washington Post*** reported on ProPublica's investigation of the APF, which detailed APF's close ties to drugmakers:

> The pills continue to have an influential champion in the American Pain Foundation, which describes itself as the nation's largest advocacy group for pain patients. Its message: The risk of addiction is overblown, and the drugs are underused.
>
> What the nonprofit organization doesn't highlight is the money behind that message.
> The foundation collected nearly 90 percent of its $5 million in funding last year from the drug and medical-device industry — and closely mirrors its positions, an examination by ProPublica found.[53]

[52] Andrea D. Furlan, et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Canadian Med. Assoc. J. 1589-94 (May 23, 2006), available at http://www.cmaj.ca/content/cmaj/174/11/1589.full.pdf (Last Accessed June 6, 2018).

[53] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, WASH POST (Dec. 23, 2011), available at https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?noredirect=on&utm_term=.7cd3b5510a53 (Last Accessed June 6, 2018).

130. **American Academy of Pain Medicine and American Pain Society**: The Defendants, including at least Endo, Janssen and Purdue, have contributed funding to the AAPM and the APS for decades.

131. In 1997, the 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. At the time, the chairman of the committee that issued the statement, Haddox, was a paid speaker for Purdue. Haddox was later hired as Purdue's vice president for health policy. The consensus statement, which also formed the foundation of the 1998 guidelines, was published on the AAPM's website. AAPM's corporate council includes Purdue, Depomed, Inc. ("Depomed"), Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

132. At or about the same time, the APS introduced the "pain as the 5th vital sign" campaign, followed soon thereafter by Veterans Affairs adopting that campaign as part of their national pain management strategy.

133. AAPM and APS issued guidelines in 2009 that continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines received funding from defendants Janssen, Cephalon, Endo or Purdue.

134. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of past abuse histories." The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; they were reprinted in the journal *Pain,* have been cited hundreds of times in academic literature and remain available online. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

135. **The Alliance for Patient Access**: 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?"[54] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006." As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes Johnson & Johnson, Endo, and Mallinckrodt.[55] A year prior, in June 2016, Purdue and Cephalon were also listed.

136. APA's board members have also directly received substantial funding from pharmaceutical companies. For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who 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, Insys, Purdue and Cephalon.[56] Nalamachu's clinic was raided by Federal Bureau of Investigation ("FBI") agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[57] 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 defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

137. Among its activities, the APA issued a white paper titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[58] Among other things, the white paper criticizes prescription

[54] *About AfPA*, AFPA (2018), available at http://allianceforpatientaccess.org/about-afpa/ (Last Accessed June 6, 2018).
[55] *Associate Members and Financial Supporters*, AFPA (June 2018), available at http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2018/06/AfPADonorsJune2018.pdf (Last Accessed June 6, 2018).
[56] Charles Ornstein, *et al.*, *Dollars for Docs*, PROPUBLICA (Dec. 13, 2016), available at https://projects.propublica.org/docdollars/ (Last Accessed June 6, 2018).
[57] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, KANSAS CITY STAR (July 20, 2017), available at http://www.kansascity.com/news/business/health-care/article162569383.html (Last Accessed June 6, 2018).
[58] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, INSTITUTE FOR PATIENT ACCESS (Oct. 2013), available at http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf (Last Accessed June 6, 2018).

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, 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.

138. 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."

139. 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.

140. In conclusion, the white paper states that "Prescription 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."

141. 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.[59]

142. The APA also worked to promote policies to limit low-enforcement oversight of opioid distribution. 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 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act").[60] The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill "could actually result in increased diversion, abuse, and public health and safety consequences"[61] and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to defend prosecutions of manufacturers and distributors, like the defendants here, in the federal courts." The law passed both houses of Congress and was signed into law in 2016.

143. *Exposing the Financial Ties Between Opioid Manufacturers and Third Party Groups:* A February 12, 2018 report, titled "Fueling an Epidemic Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups" and issued by the U.S. Senate Homeland Security & Government Affairs Committee, Ranking Member's Office, sheds additional light on the financial connections between opioid manufacturers and purportedly neutral patient advocacy organizations and medical professional societies that, unsurprisingly, have "echoed and amplified messages favorable to increased opioid use — and ultimately the financial interests of opioid manufacturers."

[59] Mary Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda,* HEALTH NEWS REVIEW (Oct. 2, 2017), available at https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ (Last Accessed June 6, 2018).

[60] Letter from Alliance for Patient Access, *et al.*, to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015).

[61] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (Oct. 17, 2017), available at https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (Last Accessed June 6, 2018).

144. The report details findings resulting from subpoenas issued by Senator McCaskill to five opioid manufacturers, including three of the Manufacturer Defendants — Purdue, Janssen, Insys, Depomed and Mylan N.V. ("Mylan") — and to 15 purportedly neutral patient advocacy organizations and medical professional societies. "The information produced to the Committee demonstrates that many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers," the report found. It continued: "Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."

145. The five manufacturers whose information was subpoenaed by Senator McCaskill alone contributed almost $9 million combined to patient advocacy organizations and professional societies operating in the opioids policy area:

	PURDUE	JANSSEN	DEPOMED	INSYS	MYLAN	TOTAL
Academy of Integrative Pain Management	$ 1,091,025	$ 128,000	$ 43,492	$ 3,050	$ -	$ 1,265,567
American Academy of Pain Medicine	$ 725,585	$ 83,975	$ 332,100	$ 57,750	$ -	$ 1,199,410
AAPM Foundation	$ -	$ -	$ 304,605	$ -	$ -	$ 304,605
ACS Cancer Action Network	$ 168,500	$ -	$ -	$ -	$ -	$ 168,500
American Chronic Pain Association	$ 312,470	$ 50,000	$ 54,670	$ -	$ -	$ 417,140
American Geriatric Society	$ 11,785	$ -	$ -	$ -	$ -	$ 11,785
American Pain Foundation	$ 25,000	$ -	$ -	$ -	$ -	$ 25,000
American Pain Society	$ 542,260	$ 88,500	$ 288,750	$ 22,965	$ 20,250	$ 962,725
American Society of Pain Educators	$ 30,000	$ -	$ -	$ -	$ -	$ 30,000
American Society of Paint Management Nursing	$ 242,535	$ 55,178	$ 25,500	$ -	$ -	$ 323,213
The Center for Practical Bioethics	$ 145,095	$ 18,000	$ -	$ -	$ -	$ 163,095
The National Pain Foundation	$ -	$ -	$ -	$ 562,500	$ -	$ 562,500
U.S. Pain Foundation	$ 359,300	$ 41,500	$ 22,000	$ 2,500,000	$ -	$ 2,922,800
Washington Legal Foundation	$ 500,000	$ -	$ -	$ -	$ -	$ 500,000
TOTALS	$ 4,153,554	$ 465,153	$ 1,071,117	$ 3,146,265	$ 20,250	$ 8,856,339

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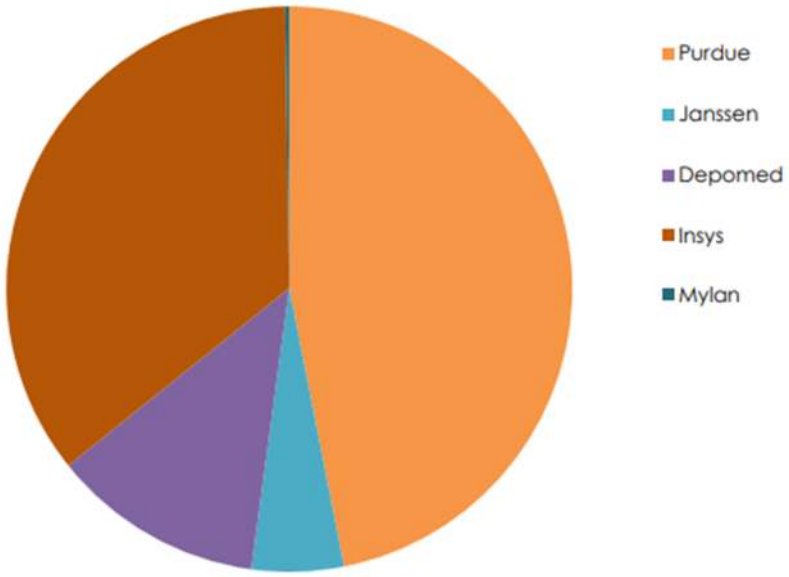
[62] HSGAC, FUELING AN EPIDEMIC: REPORT TWO, *supra* n. 18. For reasons of legibility, the chart included above is a reproduction of the chart contained in the original report in which figures have been rounded to the nearest dollar.

146. As shown below, payments from Purdue comprise roughly half this funding, with Insys providing the second-largest amount:

FIGURE 2: Percentages of Total Payments by Manufacturer, 2012-2017



[63]

147. While Purdue's payments slowed starting in 2016, Insys' payments increased exponentially in 2017:

FIGURE 3: Manufacturer Yearly Payment Totals, 2012-2017

	2012	2013	2014	2015	2016	2017	Total
Purdue	$824,227.86	$973,328.00	$812,451.95	$935,344.00	$558,067.52	$50,135.00	$4,153,554.33
Janssen	$239,902.85[36]	$99,250.00	$126,000.00				$465,152.85
Depomed	$73,080.00	$135,300.00	$113,600.00	$350,000.00	$318,257.47	$80,879.48	$1,071,116.95
Insys	$14,040.00	$68,000.00	$34,200.00	$530,025.00		$2,500,000.00	$3,146,265.00
Mylan				$15,000.00	$2,500.00	$2,750.00	$20,250.00
Total	$1,151,250.71	$1,275,878.00	$1,086,251.95	$1,830,369.00	$878,824.99	$2,633,764.48	$8,856,339.13

148. In addition to the nearly $9 million in payments to purportedly neutral patient advocacy organizations and medical professional societies, the five subpoenaed opioid manufacturers made an additional $1.6 million in payments to the organizations' and societies' group executives, staff members, board members and advisory board members. When payments

[63] *Id.*

from all opioid manufacturers are tabulated, more than $10.6 million was paid to individuals affiliated with such organizations and societies from 2013 through the date of the report:

FIGURE 8: Payments from All Opioid Manufacturers to Group-Affiliated Individuals, 2013-Present[52]

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	$8,307,243.47
AAPM Foundation	$798,051.22
American Society of Pain Educators	$749,564.78
American Academy of Pain Medicine	$204,631.53
American Pain Society	$187,699.34
ACS Cancer Action Network	$154,578.09
American Chronic Pain Association	$145,861.30
Academy of Integrative Pain Management	$82,596.98
The Center for Practical Bioethics	$16,945.88
American Geriatrics Society	$7,548.35
U.S. Pain Foundation	$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	$10,654,859.85

149. Included in the above-listed payments were payments of more than $140,000 from opioid manufacturers, including Endo, Purdue and Mallinckrodt, to ten members of the American Chronic Pain Association Advisory Board; $170,000 from Insys to National Pain Foundation ("NPF") chairman and founder D. Daniel Bennett; and more than $950,000 to members of the NPF board of directors from various opioid manufacturers, including more than $250,000 from Insys alone.

150. More concerning still, the organizations provided limited disclosures of these sources of funding - when they provided any information at all. The American Society of Pain Educators, the NPF, and the Academy of Integrative Pain Management provided no information regarding their policies for disclosing donors or donations, while several others stated explicitly that they did not disclose any information concerning donor relationships. When the groups investigated did disclose their sources of funding, they did so without providing specific donation amounts.

151. Most importantly, many of the groups investigated "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." Several of the groups "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." The report provided details regarding four ways the groups investigated set about these tasks.

152. First, the report states that "[m]any of the groups have issued guidelines to physicians and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use of opioids to treat chronic pain." The report provides examples, including: (i) the AAPM's and APS' s 1997 consensus statement endorsing opioids for chronic pain and stating that the risk of addiction was low; (ii) the 2009 issuance of guidelines by the AAPM and the APS allegedly promoting opioids as safe and effective for chronic pain and concluding the risk of addiction was manageable regardless of past abuse history; (iii) the 2009 issuance of guidelines by the American Geriatrics Society ("AGS") for the management of persistent pain recommending that opioids should be considered for all patients with moderate to severe pain in older patients and stating that the risks of addiction are exceedingly low in older patients; and (iv) the creation of a 2009 patient education guide by the AGS, the AAPM and Janssen stating that opioids are rarely addictive when used properly to manage chronic pain.

153. Second, the report notes that "[a]dvocacy groups have engaged in extensive lobbying efforts to either defeat legislation restricting opioid prescribing or promote laws encouraging opioid treatment with pain." For example, in 2014 the Academy of Integrative Pain Management and the American Cancer Society Cancer Action Network led the effort to protect a law making it difficult to discipline doctors for overprescribing opioids and prohibited doctors from refusing to prescribe opioids unless they also referred the patient to an "opioid-friendly" doctor.

154. Third, the report admonished a majority of the groups for strongly criticizing CDC guidelines issued in 2016 providing prescribing recommendations for primary care doctors who are prescribing opioids for chronic pain outside of active treatment of cancer, palliative care and end-of life care. These guidelines were "the first national standards for prescription painkillers" and were "perhaps the first major step from the federal government [] toward limiting opioid prescriptions for chronic pain in the face of an unprecedented public health crisis." However, most industry groups opposed the guidelines. For example, David Carr, the immediate past president of the AAPM, criticized the guidelines as reflecting "disproportionately strong recommendations based

upon a narrowly selected portion of the available clinical evidence." Other groups complained that draft guidelines "were not transparent," cited purported conflicts of interest among those who created them, criticized the "overly secretive manner" in which they'd been developed, and called them "inherently biased."

155. Fourth, several of the advocacy groups and professional societies organized legal efforts to challenge government actions to punish executives responsible for fraudulent opioid marketing and doctors who overprescribed opioids. For example, the NPF submitted an *amicus* brief to the U.S. Court of Appeals for the Fourth Circuit in support of a doctor convicted of 16 counts of drug trafficking for prescribing massive quantities of oxycodone and other narcotics — in one instance, more than 1,600 per day — to patients in chronic pain. In its brief, the NPF opposed the conviction, criticizing the holding that "a doctor acting in the good faith belief that he was serving the best medical interest of his patient could be found to be a drug dealer." The Washington Legal Foundation filed an *amicus* brief in the U.S. Court of Appeals for the District of Columbia Circuit arguing that the exclusion of three former Purdue executives from participation in federal healthcare programs for 12 years for their admitted failure to prevent fraudulent marketing of OxyContin raised "serious constitutional due process concerns."

156. In conclusion, the report found that, while health advocacy organizations are "among the most influential and trusted stakeholders in U.S. health policy," the reality is that their "positions closely correspond to the marketing aims of pharmaceutical and device companies," including in the area of opioids policy. "The findings in this report indicate that this tension exists in the area of opioids policy — that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use." This amplification "may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."

1. The Manufacturer Defendants Paid Key Opinion Leaders and Sponsored Speakers' Bureaus to Disseminate False and Misleading Messaging

157. The Manufacturer Defendants have paid millions of dollars to physicians to promote aggressive prescribing of opioids for chronic pain.[64] Recently released federal data shows that the Manufacturer Defendants increased such payments to physicians who treat chronic pain even while the opioid

[64] Aaron Kessler, Elizabeth Cohen and Katherine Grise, *The more opioids doctors prescribe, the more money they make*, CNN (Mar. 12, 2018), available at

epidemic accelerated and overdose deaths from prescription opioids and related illicit drugs, such as heroin, soared to record rates.[65] These payments come in the form of consulting and speaking fees, free food and beverages, discount coupons for drugs and other freebies. The total payments from the Manufacturer Defendants to doctors related to opioids doubled from 2014 to 2015. Moreover, according to experts, research shows even small amounts of money can have large effects on doctors' prescribing practices. Physicians who are high prescribers are more likely to be invited to participate in defendants' speakers' bureaus. According to a study published by the U.S. National Institutes of Health, "[i]n the speakers' bureau system, physicians are recruited and trained by pharmaceutical, biotechnology, and medical device companies to deliver information about products to other physicians, in exchange for a fee."[66]

158. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. According to a 2013 publication by the Institute on Medicine as a Profession, speakers' bureaus are ethically compromised because they often present information as objective when it is heavily biased toward the interests of the industry sponsor and, in fact, may lead to the dissemination of false or biased information. These findings are substantiated by citations to research in *JAMA, The Journal of Law, Medicine & Ethics* and *Academic Psychiatry.*

> **The Problem:**
>
> ***Pharmaceutical companies often recruit physicians to perform speeches or presentations for the purpose of marketing a specific drug. In 2010, 8.6% of physicians reported having received payments for participating in speakers' bureaus.*** These speakers' bureaus leverage the credibility of physicians in order to promote the use of pharmaceutical products. ***The physicians are generally trained to present a certain message, or are provided with pre-produced slides. The audience may assume that these presentations are objective, when in fact they are heavily biased towards the interests of the industry sponsor.***
>
> ***Speakers' bureaus may lead to the dissemination of false or biased information.*** Exposure to industry-sponsored speaking events is associated with decreased quality of

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https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html (Last Accessed June 6, 2018).

[65] Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, PORTLAND PRESS HERALD (Dec. 25, 2016), available at https://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/ (Last Accessed June 6, 2018).

[66] Lynette Reid & Matthew Herder, *The speakers' bureau system: a form of peer selling*, 7(2) OPEN MED. e31-e39 (Apr. 2, 2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863750/ (Last Accessed June 6, 2018).

> prescribing. Additionally, the compensation provided for these engagements may influence the attitudes or judgment of the presenter."[67]

159. For example, 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 above, 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 *JAMA* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[68]

160. Similarly, 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 served as president of the AAPM and argued against legislation restricting high-dose opioid prescription for non-cancer patients. 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. He has also acknowledged having failed to disclose numerous conflicts of interest.

161. Fishman and Fine are only two of the many physicians whom the Manufacturer Defendants paid to present false or biased information on the use of opioids for chronic pain.

2. Senate Investigations of the Manufacturer Defendants

162. In May 2012, the Chair and Ranking Member of the Senate Finance Committee, Max Baucus (D-MT) and Chuck E. Grassley (R-IA), launched an investigation into makers of narcotic painkillers

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[67] *Speakers' Bureaus: Best Practices for Academic Medical Centers*, IMAP (Oct. 10, 2013), available at http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf (Last Accessed June 6, 2018).

[68] 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), available at https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (Last Accessed June 6, 2018).

and groups that champion them. The investigation was triggered by "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers," including popular brand names like OxyContin, Vicodin and Opana.

163. The Senate Finance Committee sent letters to Purdue, Endo and Johnson & Johnson, as well as five groups that support pain patients, physicians or research, including the APF, AAPM, APS, University of Wisconsin Pain & Policy Studies Group and the Center for Practical Bioethics. Letters also went to the FSMB and the Joint Commission.

164. As shown below in an excerpt from the Senators' letter to APF, the Senators addressed the magnitude of the epidemic and asserted that mounting evidence supports that the pharmaceutical companies may be responsible:

> ***It is clear that the United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers such as Oxycontin (oxycodone), Vicodin (hydrocodone), Opana (oxymorphone).*** According to CDC data, "more than 40% (14,800)" of the "36,500 drug poisoning deaths in 2008" were related to opioid-based prescription painkillers. Deaths from these drugs rose more rapidly, "from about 4,000 to 14,800" between 1999 and 2008, than any other class of drugs, [killing] more people than heroin and cocaine combined. ***More people in the United States now die from drugs than car accidents as a result of this new epidemic. Additionally, the CDC reports that improper "use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs."***
>
> * * *
>
> Concurrent with the growing epidemic, the *New York Times* reports that, based on federal data, ***"over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks" while "data suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses."***
>
> ***There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness***. Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Academy of Pain Medicine, the Federation of State Medical Boards, and University of Wisconsin Pain and Policy Study Group, and the Joint Commission.
>
> In a *ProPublica* story published in the *Washington Post,* the watchdog organization examined the ***American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry."*** *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers ***play down the risks associated with opioids***

> ***and exaggerate their benefits***. Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research."
> According to the *Milwaukee Journal Sentinel/MedPage Today,* ***a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers . . . helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient literature, position statements, books and doctor education courses."***
>
> Although it is critical that patients continue to have access to opioids to treat serious pain, ***pharmaceutical companies and health care organizations must distribute accurate and unbiased information about these drugs in order to prevent improper use and diversion to drug abusers.***[69]

165. The Senators demanded substantial discovery, including payment information from the companies to various groups, including the front organizations identified above, and to physicians, including Portenoy, Fishman and Fine, among others. They asked about any influence the companies had on a 2004 pain guide for physicians that was distributed by the FSMB, on the APS's guidelines and on the APF's Military Veterans Pain Initiative. Almost immediately upon the launch of the Senate investigation, the APF shut down "due to irreparable economic circumstances." The opioid report resulting from this investigation has not been released publicly.[70]

166. On March 29, 2017, it was widely reported[71] that yet another Senate investigation had been launched:

> Missouri Senator Claire McCaskill has launched an investigation into some of the country's leading prescription drug manufacturers, demanding documents and records dating back the past five years which indicate just what the companies knew of the drugs' risk for abuse as well as documents detailing marketing practices and sales presentations. Her office has sent letters to the heads of Purdue, Janssen/Johnson & Johnson, Insys, Mylan, and Depomed.

167. The above-referenced companies were reportedly targeted based on their role in manufacturing some of the opioid painkillers with the highest sales in 2015.

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[69] Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director, American Pain Society (May 8, 2012).
[70] Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed opioids report*, STAT NEWS (June 27, 2016), available at https://www.statnews.com/2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/ (Last Accessed June 6, 2018).
[71] Nadia Kounang, *Senator McCaskill opens investigation into opioid manufacturers*, CNN (Mar. 29, 2017), available at https://www.cnn.com/2017/03/28/health/senate-opioid-manufacturer-investigation/index.html (Last Accessed June 6, 2018).

168. On September 6, 2017, Senator McCaskill's report, "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization" was published. The report found that Insys manipulated the prior authorization process by misleading pharmacy benefit managers about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients.[72]

169. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.
>
> Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed.[73]

170. Professor Adriane Fugh-Berman ("Fugh-Berman"), Associate Professor at Georgetown University Medical Center and director of a program at Georgetown called Pharmed Out, which conducts research on and educates the public about inappropriate pharmaceutical company marketing, also testified during the hearing. She, too, placed the blame for the opioid epidemic squarely at the feet of pharmaceutical companies:

> Since the 1990's, pharmaceutical companies have stealthily distorted the perceptions of consumers and healthcare providers about pain and opioids. Opioid manufacturers use drug reps, physicians, consumer groups, medical groups, accreditation and licensing bodies, legislators, medical boards and the federal government to advance marketing goals to sell more opioids. This aggressive marketing pushes resulted in hundreds of thousands of deaths from the overprescribing of opioids. The U.S. is about — comprises about five percent of the world population, but we use about two-thirds of the world supply of opioids.

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[72] *Fueling an Epidemic* (Report One), HSGAC (2017), available at https://www.hsgac.senate.gov/imo/media/doc/REPORT%20-%20Fueling%20an%20Epidemic%20-%20Insys%20Therapeutics%20and%20the%20Systemic%20Manipulation%20of%20Prior%20Authorization.pdf (Last Accessed June 6, 2018).

[73] *McCaskill Continues Investigation Into Opioid Crisis with Committee Roundtable on Opioids Sales and Marketing*, HSGAC (Sept. 12, 2017), available at https://www.hsgac.senate.gov/media/minority-media/mccaskill-continues-investigation-into-opioid-crisis-with-committee-roundtable-on-opioids-sales-and-marketing- (Last Accessed June 6, 2018).

171. Fugh-Berman also answered why doctors were able to be convinced by pharmaceutical companies' marketing efforts:

> Why do physicians fall for this? Well, physicians are overworked, overwhelmed, buried in paperwork and they feel unappreciated. Drug reps are cheerful. They're charming. They provide both appreciation and information. Unfortunately, the information they provide is innately unreliable.
>
> Pharmaceutical companies influence healthcare providers' attitudes and their therapeutic choices through financial incentives that include research grants, educational grants, consulting fees, speaking fees, gifts and meals.

172. Fugh-Berman further described the false information provided by pharmaceutical companies and the industry creation of front organizations, including the APF, to pass industry-influenced regulations and policies**:**

> Pharmaceutical companies convinced healthcare providers that they were opiophobic and that they were causing suffering to their patients by denying opioids to patients with back pain or arthritis. They persuaded prescribers that patients with pain were somehow immune to addiction. Even when addiction was suspected, physicians were taught that it might not really be addiction, it might be pseudo-addiction, an invented condition that's treated by increasing opioid dosages.
>
> Industry created the American Pain Foundation co-opted other groups including medical organizations, and they change state laws to eliminate curbs on opioid prescribing. Between 2006 and 2015, pharmaceutical companies and the advocacy groups they control employ 1,350 lobbyists a year in legislative hubs. Industry-influenced regulations and policies ensure that hospitalized patients were and are berated paraded constantly about their level of pain and overmedicated with opioids for that pain. Even a week of opioids can lead a patient into addiction so many patients are discharged from hospitals already dependent on opioids.

173. In addition, Fugh-Berman pointed out that promotion of opioids remains ongoing despite increasing public concern about their use:

> Promotion of opioids is not in the past. Between 2013 and 2015, one in 12 physicians took out money from opioid manufacturers, a total of more than $46 million. Industry-friendly messages that pharmaceutical companies are currently perpetuating reassure physicians that prescribing opioids is safe as long as patients do not have a history of substance abuse or mental illness.

174. Fugh-Berman concluded by stating: "It is a misperception to think that most opioid deaths are caused by misuse of opioids or overdoses. In fact, many deaths occur when people are using opioids in exactly the way they were prescribed. Misuse isn't the problem; use is the problem."

3. The Devastating Impact of the Manufacturers' Unfair and Fraudulent Sales Practices

175. The impact of the Manufacturer Defendants' false messaging has been profound. The drug companies profited handsomely as more and more people became addicted to opioids and died of overdoses.[74]

176. For Purdue, sales grew from $48 million per year in 1996, to over $1 billion per year in 2000, to $3.1 billion per year ten years later.[75] In 2011, pharmaceutical companies generated revenues of $11 billion from opioid sales alone.[76]

177. The United States, including San Mateo County, is experiencing an unprecedented opioid addiction and overdose epidemic, costing billions of dollars for, inter alia, treatment, services and public safety, as well as lost productivity in the workforce and economic opportunity. A study released on March 27, 2018 by the American Action Forum revealed that in 2015 nearly one million people in the United States between the ages of 25 and 54 were not working because they were dependent on opioid drugs, a number that had grown each year between 1999 and 2015.[77] The study calculated that the loss of employees and their productivity during that period cost the U.S. economy $702 billion, or just under $44 billion per year. The CDC estimates the total economic burden of prescription opioid misuse in the US is $78.5 billion a year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement.[78]

178. By 2002, "[l]ifetime ***nonmedical*** use of OxyContin increased from 1.9 million to 3.1 million people between 2002 and 2004, and in 2004 there were 615,000 new nonmedical users of OxyContin."

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[74] German Lopez, *How big pharma got people hooked on dangerous opioids — and made tons of money off it*, VOX (Sept. 22, 2016), available at https://www.vox.com/2016/2/5/10919360/opioid-epidemic-chart (Last Accessed June 6, 2018).

[75] Mike Mariani, *How the American Opiate epidemic was started by one pharmaceutical company*, PACIFIC STANDARD, Mar. 4, 2015, available at http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company (Last Accessed June 7, 2018).

[76] Katherin Eban, *OxyContin: Purdue Pharma's painful medicine*, FORTUNE (Nov. 9, 2011), available at http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (Last Accessed June 7, 2018).

[77] Ben Gitis & Isabel Soto, *The Labor Force And Output Consequences Of The Opioid Crisis*, AMERICAN ACTION FORUM (Mar. 27, 2018), available at https://www.americanactionforum.org/research/labor-force-output-consequences-opioid-crisis/ (Last Accessed June 7, 2018).

[78] https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#two (Last Accessed December 19, 2018).

179. By 2004, OxyContin had "become the most prevalent prescription opioid abused in the United States. The severity of the problem was first felt in states including Maine, West Virginia, eastern Kentucky, southwestern Virginia and Alabama, where, from 1998 through 2000, hydrocodone and oxycodone were being prescribed 2.5-5 times more often than the national average. By 2000, these same areas had a prescription rate up to 5-6 times higher than the national average. These areas were also the first to suffer increased abuse and diversion, which became apparent by 1999 and 2000. Manufacturers then expanded the geographic market by investing hundreds of millions of dollars in marketing, and the once-regional problem began to spread nationally. "[B]y 2004 OxyContin had become a leading drug of abuse in the United States."

180. As OxyContin sales grew between 1999 and 2002, so did sales of other opioids, including fentanyl (226%), morphine (73%) and oxycodone (402%). And, as prescriptions surged between 1999 and 2010, so did deaths from opioid overdoses: Unintentional overdose deaths from prescription opioids outnumbered those attributed to heroin and cocaine in the US as of 2002.

181. In 2012 alone, an estimated 259 million opioid prescriptions were filled, enough to medicate every adult in the United States for a month on a round-the-clock basis.[79] In 2014, there were more than 47,000 drug overdose deaths nationwide, 61% involving a prescription or illicit opioid.[80] The use of prescription painkillers cost health insurers up to $72.5 billion annually in direct healthcare costs.[81]

182. According to data from Rx Opioid Safe San Mateo, in just one year, over 24 million opioid pills were prescribed and filled for San Mateo County residents. That's 43 pills for every resident over the age of 18.[82] In 2015, nearly 350,000 opioid prescriptions were filled in San Mateo County, with the average doctor writing 100 prescriptions. The top prescriber wrote more than 3,900 prescriptions, according to

[79] *Opioid Painkiller Prescribing*, CDC (July 2014), available at https://www.cdc.gov/vitalsigns/opioid-prescribing/ (Last Accessed June 7, 2018).
[80] Rose A. Rudd, *et al.*, *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, CDC (Dec. 30, 2016), available at https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm (Last Accessed June 7, 2018).
[81] *Prescription Painkiller Overdoses in the US*, CDC (Nov. 2011), available at https://www.cdc.gov/vitalsigns/painkilleroverdoses/index.html (Last Accessed June 7, 2018).
[82] *Stay Rx Opioid Safe*, SMC HEALTH (2018), available at https://www.smchealth.org/sites/main/files/file-attachments/rxopioid_safe_flyer.pdf (Last Accessed June 7, 2018).

County health officials.[83] San Mateo County experienced 60 drug-induced deaths in 2015, with approximately 20 tied directly to Opioids.

183. San Mateo County has seen a steady increase in deaths from opioids in recent years. Like other counties, San Mateo County now spends millions of dollars each year dealing with the fallout of the opioid epidemic. San Mateo County's ongoing costs include costs related to drug treatment, emergency room visits, law enforcement, and social services (including for children born opioid-dependent and/or have parents who are unable to care for them because of their own addiction).

184. According to the most recent data available, in 2017, 97 San Mateo County residents died from drug related causes with ***11 deaths directly tied to heroin use and another 26 deaths directly tied to other opioids***. In sum, 37 deaths in 2017 in San Mateo County were related to heroin or other opioids, which is 38% of all drug-related deaths. If anything, these statistics are conservative because of the complex nature of opioid abuse: the County is expected to directly attribute additional deaths, currently attributed elsewhere, to opioids. In the prior year, 2016, 61 deaths were drug related, with 11 related to heroine and 16 related to other opioids.

185. These deaths represent the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 nonmedical users. And as reported in May 2016, in California, opioid overdoses resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

186. Between 2010 and 2014, opioids accounted for ***almost half of all filled scheduled drug prescriptions***. In 2015 there were an estimated ***hundreds of thousands of opioid prescriptions*** filled in San Mateo County, a figure that has gone up each year since. County health officials estimate that thousands of residents are opioid dependent.

[83] Samantha Weigel, *County, doctors confront opioid abuse: Physicians urged to be cautious with how they prescribe medication*, SM DAILY JOURNAL (Apr. 24, 2017), available at https://www.smdailyjournal.com/news/local/county-doctors-confront-opioid-abuse-physicians-urged-to-be-cautious/article_77e8b7a0-c6ed-5ce4-99c9-eb12d57d0790.html (Last Accessed June 7, 2018).

187. The year 2017 saw a total of 54 opioid-related overdose ambulance calls. This was an increase year-over-year from 2016's 50 overdose calls.

188. In Fiscal-Year 2016-2017 the San Mateo County Health System provided drug treatment services to 456 individuals addicted to heroin and 123 individuals addicted to other opiates for a total of 579 individuals.

189. San Mateo County continues to suffer significant financial consequences as a result of opioid over-prescription and addiction, including, but not limited to, increased law enforcement and judicial expenditures, increased jail expenditures, increased substance abuse treatment and diversion plan expenditures, increased emergency and medical care services, increased health insurance costs and lost economic opportunity.

190. The seriousness of the Opioid Epidemic initially compelled the police department in San Bruno, a city in San Mateo County, to issue kits with Naloxone to all sworn officers, to care for victims of opioid overdoses—including addicts on the street—before paramedics can arrive at the scene. But the problem became so severe and pervasive that the San Mateo County Sheriff's Office, through the San Mateo County Narcotics Task Force, has begun issuing Naloxone to its officers on a countywide basis.[84]

191. Through this litigation San Mateo County is doing its part to address the opioid epidemic through the two tools available: injunctive relief and damages. However, it is important not to lose sight of the human side of this tragedy – behind every death, and every dollar spent on the epidemic there is a human life and a family that irreparably harmed.

C. THE MANUFACTURER DEFENDANTS' SPECIFIC UNLAWFUL PRACTICES THAT TARGETED SAN MATEO COUNTY PRESCRIBERS

1. Purdue

192. Purdue manufactures, markets, sells and distributes opioids in San Mateo County and nationwide, including the following products, each of which is Schedule II:

[84] Press Release, San Mateo County Sherriff's Office (Oct. 15, 2018), *available at* https://www.smcsheriff.com/sites/default/files/articles/Narcan%20all.pdf.

OxyContin (oxycodone hydrochloride extended release)	Opioid agonist indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment; not indicated as an as-needed (p.r.n.) analgesic. It was first approved by the FDA in December 1995.
MS Contin (morphine sulfate extended release)	Opioid agonist; controlled-release tablet form of morphine sulfate indicated for the management of severe pain; not intended for use as a p.r.n. analgesic; first approved in May 1987 as the first formulation of an opioid pain medicine that allowed dosing every 12 hours.
Dilaudid (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral formulation; eight times more potent than morphine.[85]
Dilaudid-HP (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral high-potency and highly concentrated formulation indicated for relief of moderate-to-severe pain in opioid-tolerant patients.
Hysingla ER (hydrocodone bitrate)	Brand-name extended-release form of hydrocodone bitrate that is indicated for the management of severe pain.
Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride)	Brand-name extended-release opioid analgesic made of a combination of oxycodone hydrochloride and naloxone hydrochloride. It was approved by the FDA on July 23, 2013.

193. According to public records compiled by ProPublica, in 2015 alone, Medicare Part D paid $85.6 million for claims arising from California physicians' OxyContin prescriptions.[86]

a. Purdue Falsely Marketed Extended-Release Drugs as Safer and More Effective than Regular-Release Drug

[85] *Dilaudid Addiction*, SUBXONE CALIFORNIA (2018), available at https://www.suboxonecalifornia.com/%20suboxone-treatment/dilaudid-addiction/ (Last Accessed June 7, 2018).

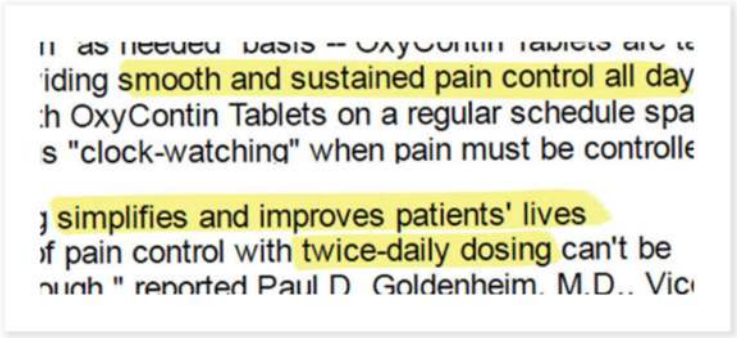
[86] Prescriptions subsidized by Medicare Part D comprise only a fraction of prescriptions for OxyContin and other opioids in California.

194. Purdue launched OxyContin 20 years ago with a bold marketing claim: "One dose relieves pain for 12 hours, more than twice as long as generic medications "[87]

1996

OxyContin Press Release

When Purdue unveiled OxyContin in 1996, it touted 12-hour duration.

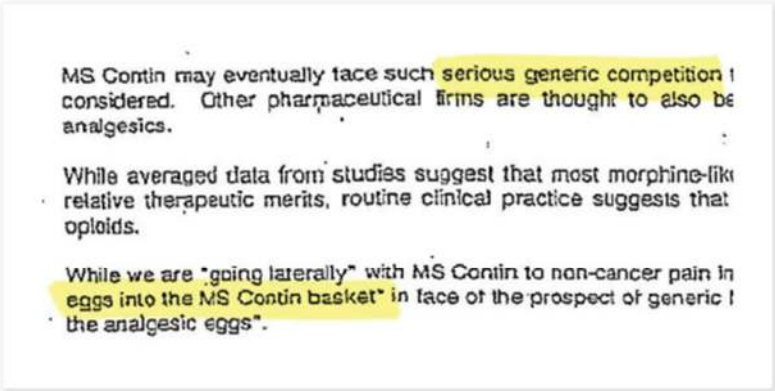


195. Prior to launching OxyContin, Purdue conducted focus groups with doctors and "learned that the 'biggest negative' that might prevent widespread use of the drug was ingrained concern regarding the 'abuse potential' of opioids."

1990

Purdue's Need for a New Painkiller

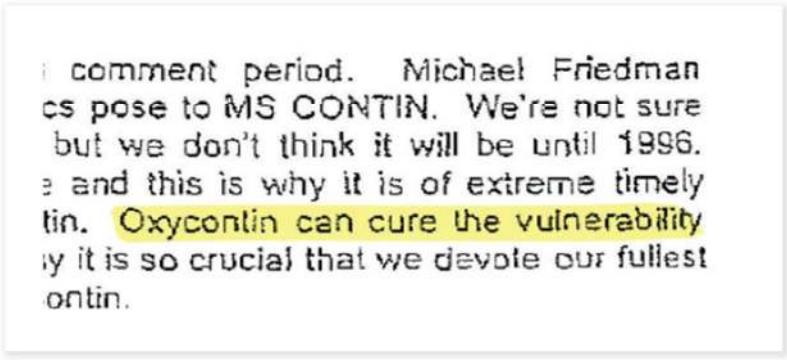
In this 1990 memo, Robert Kaiko, the scientist who would go on to help invent OxyContin, explains why Purdue needs another painkiller.



1995

OxyContin Launch

At a 1995 meeting, Purdue executives described how OxyContin could "cure" the "vulnerability" of generic competition and laid out how they planned to market the drug.



[87] Harriet Ryan, Lisa Girion & Scott Glover, *"You Want A Description of Hell?" OxyContin's 12-Hour Problem*, L.A. TIMES (May 5, 2016), available at http://www.latimes.com/projects/oxycontin-part1/ (Last Accessed June 7, 2018).

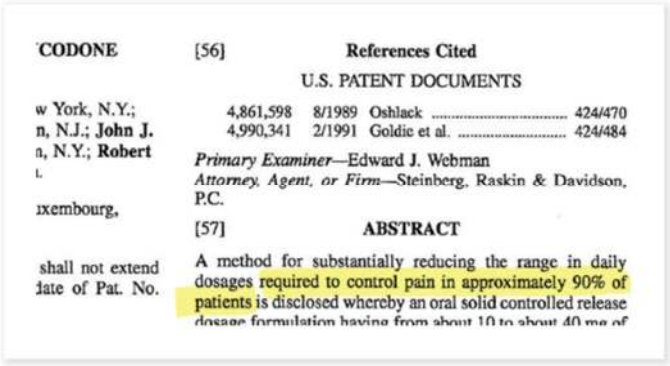
196. In its initial press release launching the drug, Purdue told doctors that one OxyContin tablet would provide "smooth and sustained pain control all day and all night." Based in large part on that promise, and on Purdue's repeated assurances that opioids were both effective and nonaddictive, OxyContin became America's best-selling painkiller.[88] Purdue had no evidentiary basis for its claims. Though the FDA's 1995 approval allowed Purdue to include a package insert for OxyContin declaring the drug to be safer than its competitors' opioids due to its delayed release design, Purdue had in fact "conducted no clinical studies on how addictive or prone to abuse the drug might be. . . . The FDA examiner who oversaw the process, Dr. Curtis Wright, left the agency shortly afterward. Within two years, he had taken a job at Purdue."

197. In its 1992 patent application, Purdue falsely claimed OxyContin controlled pain in 90% of patients for 12 hours:

1992

OxyContin Patent

Applying for a patent in 1992, Purdue said OxyContin controlled pain for 12 hours "in approximately 90% of patients."



'CODONE

w York, N.Y.; n, N.J.; **John J.** n, N.Y.; **Robert**

uxembourg,

shall not extend date of Pat. No.

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,861,598	8/1989	Oshlack	424/470
4,990,341	2/1991	Goldie et al.	424/484

Primary Examiner—Edward J. Webman
Attorney, Agent, or Firm—Steinberg, Raskin & Davidson, P.C.

[57] **ABSTRACT**

A method for substantially reducing the range in daily dosages required to control pain in approximately 90% of patients is disclosed whereby an oral solid controlled release dosage formulation having from about 10 to about 40 mg of

198. In truth, Purdue's nationwide marketing claims were false and highly deceptive. OxyContin was not superior to immediate-release opioids. And not only does OxyContin wear off early, as Purdue's own early studies showed, it is highly addictive:

> OxyContin's stunning success masked a fundamental problem: The drug wears off hours early in many people, a Los Angeles Times investigation found. ***OxyContin is a chemical cousin of heroin, and when it doesn't last, patients can experience excruciating symptoms of withdrawal, including an intense craving for the drug***.

199. The Los Angeles Times investigation, reported in three parts on May 5, July 10 and December 18, 2016, included the review of thousands of pages of confidential Purdue documents

[88] 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*, PR NEWSWIRE (May 31, 1996).

and court and other records. They span three decades, from the conception of OxyContin in the mid-1980s to 2011, and include e-mails, memoranda, meeting minutes and sales reports, as well as sworn testimony by executives, sales representatives and other employees. The Los Angeles Times reporters also examined FDA records, Patent Office files and medical journal articles, and interviewed experts in pain treatment, addiction medicine and pharmacology. Furthermore, experts call the 12-hour dosing "an addiction producing machine".

200. Purdue had reportedly known for decades that it falsely promised 12-hour relief and nevertheless mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing:

- Even before OxyContin went on the market, ***clinical trials showed many patients weren't getting 12 hours of relief.*** Since the drug's debut in 1996, the company has been confronted with additional evidence, including complaints from doctors, reports from its own sales representatives and independent research.
- The company has held fast to the claim of 12-hour relief, in part to protect its revenue. OxyContin's market dominance and its high price — up to hundreds of dollars per bottle — hinge on its 12-hour duration. Without that, it offers little advantage over less expensive painkillers.
- When many doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue executives mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing. Anything shorter "needs to be nipped in the bud. NOW!!" one manager wrote to her staff.
- Purdue tells doctors to prescribe stronger doses, not more frequent ones, when patients complain that OxyContin doesn't last 12 hours. That approach creates risks of its own. Research shows that the more potent the dose of an opioid such as OxyContin, the greater the possibility of overdose and death.
- **More than half of long-term OxyContin users are on doses that public health officials consider dangerously high**, according to an analysis of nationwide prescription data conducted for The Times.

201. Here is an example of an advertisement in a medical journal circa 1997:

A 1997 OxyContin advertisement in the American Family Physician shows marketing promoting the benefits of 12-hour dosing. (Liz. O. Baylen / Los Angeles Times)

202. Purdue gave away promotional materials to doctors to display in their offices touting the claimed 12 hour pain relief, including this clock:

A clock that Purdue distributed to doctors and healthcare professionals to promote OxyContin. (Liz. O. Baylen / Los Angeles Times)

203. As reported by *The New York Times,* "internal Purdue Pharma documents show that company officials recognized even before the drug was marketed that they would face stiff resistance from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be abused by patients or cause addiction."[89] To combat this resistance, Purdue promised the long-acting, extended-release formulation as safer and "less prone to such problems."

b. Purdue Falsely Marketed Low Addiction Risk to Wide Swaths of Physicians

[89] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES (May 10, 2007), available at https://www.nytimes.com/2007/05/10/business/11drug-web.html (Last Accessed June 7, 2018).

204. In addition to pushing OxyContin as safe and non-addictive by equating extended-release with a lower risk, Purdue also promoted the use of prescription opioids for use in non-cancer patients, who make up 86% of the total opioid market today.

205. Rather than targeting merely those physicians treating acute severe short-term (like post-operative) pain or oncologists treating end-stage cancer pain, reports indicate that Purdue heavily promoted OxyContin nationwide to doctors such as general practitioners, who often had little training in the treatment of serious pain or in recognizing signs of drug abuse in patients. According to a report in *The New Yorker,* "[a] major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or cancer but also for less acute, longer-lasting pain: arthritis, back pain, sports injuries, fibromyalgia" and "[t]he number of conditions that OxyContin could treat seemed almost unlimited."

206. Sales representatives plied these and other physicians with coupons that were redeemable for a 7- to 30-day supply of free OxyContin, a Schedule II narcotic that by definition cannot be prescribed for more than one month at a time, with the promise that OxyContin was a safe opioid. Purdue "trained its sales representatives to carry the message that the risk of addiction was `less than one percent,' and "[a] consistent feature in the promotion and marketing of OxyContin was a systematic effort to minimize the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain."

207. Sales representatives marketed OxyContin as a product "to start with and to stay with," and Purdue deliberately exploited a misconception it knew many doctors held that oxycodone was less potent than morphine. 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. *The New Yorker* reported that "[i]n 2002, a sales manager from the company, William Gergely, told a state investigator in Florida that Purdue executives 'told us to say things like it is "virtually" non-addicting.' "

208. Further, "[a]ccording to training materials, Purdue instructed sales representatives to assure doctors — repeatedly and without evidence — that 'fewer than one per cent' 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.)"

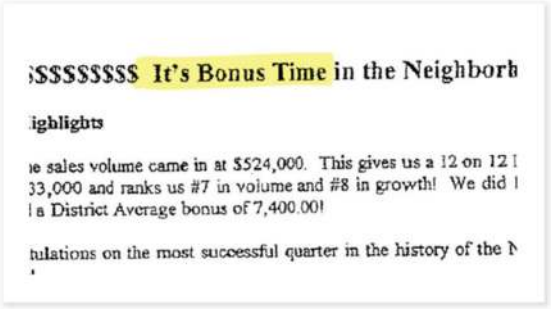
209. Even as late as 2015, if not later, Purdue sales representatives were telling physicians OxyContin was addiction resistant and had 'abuse deterrent' properties."

210. While pumping out false information about the properties of OxyContin, Purdue pushed its sales force to sell more and more prescriptions:

1996

Letter to Sales Reps

In this 1996 memo entitled "It's Bonus Time in the Neighborhood," a Purdue sales manager told her staff to talk up stronger doses of OxyContin in conversations with doctors.



$$$$$$$$ It's Bonus Time in the Neighborh

ighlights

ıe sales volume came in at $524,000. This gives us a 12 on 12 I
33,000 and ranks us #7 in volume and #8 in growth! We did I
l a District Average bonus of 7,400.00!

tulations on the most successful quarter in the history of the N

211. The marketing worked. Keith Humphreys, Professor of Psychiatry at Stanford and drug-policy adviser to the Obama Administration, said, "[t]hat's the real Greek tragedy of this — that so many well-meaning doctors got co-opted. The level of influence is just mind-boggling. Purdue gave money to continuing medical education, to state medical boards, to faux grassroots organizations."

212. Purdue also tracked physicians' prescribing practices by reviewing pharmacy prescription data it obtained from I.M.S. Health, a company notably co-founded by Arthur Sackler, who arranged financing for his brother's purchase of Purdue in 1952, that buys bulk prescription data from pharmacies and resells it to drug makers for marketing purposes. Rather than reporting highly suspicious prescribing practices, Purdue used the data to track physicians who prescribed some opioids and might be persuaded to prescribe more. Purdue also could identify physicians writing large numbers of prescriptions, and particularly for high-dose 80 mg pills — potential signs of diversion and drug dealing.[90] It called the high-prescribing doctors "whales." An 80 mg tablet is equivalent in strength to 16 Vicodin tablets, and was generally reserved by doctors for patients with severe, chronic pain who had built up a tolerance over months or years. In the illegal drug trade, however, "80s" were the most in demand. For those attempting to detect how OxyContin was getting onto the black market, a physician writing a high volume of 80s was a red flag.

[90] Harriet Ryan, Lisa Girion & Scott Glover, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, LA TIMES (July 10, 2016), available at http://www.latimes.com/projects/la-me-oxycontin-part2/ (Last Accessed June 7, 2018).

213. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from sales representatives and, in some instances, its own surveillance operations.[91] Purdue's "Abuse and Diversion Detection" program requires its sales representatives to report to the company any facts that suggest a healthcare provider to whom it markets opioids may be involved in the abuse or illegal diversion of opioid products. When a provider is reported under the program, Purdue purportedly conducts an internal inquiry regarding the provider to determine whether he or she should be placed on a "no-call" list. If a provider is placed on this list, Purdue sales representatives may no longer contact the provider to promote the company's opioid products. Since 2002, Purdue maintained a confidential roster of suspected reckless prescribers known as "Region Zero." By 2013, there were more than 1,800 doctors in Region Zero, but Purdue had reported only 8% of them to authorities. The *Los Angeles Times* reported that "[a] former Purdue executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores."

c. Purdue Funded Publications and Presentations with False and Misleading Messaging

214. As explained above, Purdue's false marketing scheme did not end with its own sales representatives and branded marketing materials. It extended far beyond, engaging third parties including doctors and front groups to spread the false message of prescription opioids' safety and efficacy.

215. Purdue caused the publication and distribution of false and deceptive guidelines on prescribing opioids. For example, as set forth above, Purdue paid $100,000 to the FSMB to help print and distribute its guidelines on the use of opioids to treat chronic pain to ***700,000*** practicing doctors; among the FSMB's members are the Medical Board of California and the Osteopathic Medical Board of California.

216. One of the advisors for Fishman's 2007 publication "Responsible Opioid Prescribing: A Physician's Guide" and its 2012 update was Haddox, a longtime member of Purdue's speakers' bureau who later became a Purdue vice president.

[91] Bill Fallon, *Purdue Pharma agrees to restrict marketing of opioids*, STAMFORD ADVOCATE (Aug. 25, 2015), available at https://www.stamfordadvocate.com/business/article/Purdue-Pharma-agrees-to-restrict-marketing-of-6464800.php (Last Accessed June 7, 2018).

217. Similarly, multiple videos feature 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.[92] He states 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 entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He 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 by doctors and evaluated with "tools," but leaves that for "a whole other lecture."

218. Purdue provided many "teaching" materials free of charge to the Joint Commission.

219. Purdue also deceptively marketed the use of opioids for chronic pain through the APF, which was shut down after the U.S. Senate investigation launched in 2012. In 2010 alone, the APF received 90% of its funding from drug and medical device companies, including from Purdue. Purdue paid APF unspecified amounts in 2008 and 2009 and between $100,000 and $499,999 in 2010.[93]

1. The Guilty Pleas

220. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman ("Friedman"), the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell ("Udell"), Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim ("Goldenheim"), its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

[92] Perry Fine, M.D., *Safe and Effective Opioid Rotation*, ONLINE SYMPOSIA (Nov. 8, 2012), available at https://www.youtube.com/watch?v=_G3II9yqgXI (Last Accessed June 7, 2018).
[93] *American Pain Foundation* GUIDESTAR (2018), available at https://www.guidestar.org/profile/52-2002328 (Last Accessed June 7, 2018).

221. In a statement announcing the guilty plea, John Brownlee ("Brownlee"), the U.S. Attorney for the Western District of Virginia, stated:

> **Purdue claimed it had created the miracle drug — a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. *Purdue's marketing campaign worked, and sales for OxyContin skyrocketed — making billions for Purdue and millions for its top executives.***
>
> ***But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false — and Purdue knew its claims were false. The result of their misrepresentations and crimes sparked one of our nation's greatest prescription drug failures. . . .* OxyContin was the child of marketeers and bottom line financial decision making.**[94]

222. Brownlee characterized Purdue's criminal activity as follows:

> **First, *Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse.* Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.**
> **Second, *Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction* than immediate-release opioids.**
> **Third, *Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse* than short-acting opioids.**
> **Fourth, *Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance* to the drug.**
> **And fifth, *Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids,* and could be used to "weed out" addicts and drug seekers.**

223. Specifically, Purdue pleaded guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Friedman, Udell and Goldenheim pleaded guilty to the misdemeanor charge of misbranding OxyContin, for introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§331(a), 333(a)(1)-(2) and 352(a).

[94] *Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and its Executives for Illegally Misbranding OxyContin*, DOJ (May 10, 2007), available at http://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf (Last Accessed June 7, 2018).

224. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were effective and non-addictive. Purdue continues to aggressively market the liberal prescribing of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly $900,000,000 on lobbying and political contributions — eight times what the gun lobby spent during that period.

225. Purdue has earned more than $31 billion from OxyContin, which, as the nation's best-selling painkiller, constitutes approximately 30% of the United States market for painkillers. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up threefold from 2006 sales of $800 million.

226. Purdue also made payments to physicians nationwide for activities including participating in speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance, and other services,[95] including, on information and belief, to San Mateo County physicians.

2. Purdue Failed to Report Suspicious Sales as Required

227. The Controlled Substances Act, and the regulations promulgated thereunder, 21 C.F.R. §1300 *et seq.,* imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b). The CSA's requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o).

228. Purdue is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

[95] GAO, *supra* n.44 at 18, 21, 26–28.

229. The California Code of Regulations requires all drug manufacturers and wholesalers to report "all sales of dangerous drugs subject to abuse" to the Board of Pharmacy (the "Board") up to 12 times per year, pursuant to the Board's request. 16 C.C.R. §1782.

230. Purdue failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Purdue also failed to report to the Board sales of dangerous drugs subject to abuse. Purdue's failure to timely report these and other suspicious sales violated the CSA and California law.

d. Purdue's Board of Directors and Executives Are Personally Liable Because They Were Intimately Involved With, Directed, and Profited From the Companies' Misconduct

231. Purdue's directors and executives—predominately members of the Sackler family—had oversight and control over the unlawful sales and marketing conduct at issue in this Complaint, and they are lawful for the misconduct because they: (a) participated in the misconduct and/or (b) knew about the misconduct and failed to stop it and/or (c) should have known about the misconduct and failed to stop it.

i. A Small Group of Sackler Family Directors and Other Senior Corporate Leaders Controlled Purdue and Profited From It, Running Purdue as Their Personal Enterprise

232. Richard Sackler, Jonathan Sackler, Beverly Sackler, Mortimer Sackler, Kathe Sackler, Ilene Sackler Lefcourt, and David Sackler hold seats on the Board of Directors of Purdue Pharma Inc. Their family owns the company. Richard, Jonathan, Beverly, Mortimer, Kathe, and Ilene have been on the board since the 1990s. David has been on the board since 2012.

233. Richard Sackler was as an inventor of the original patent for OxyContin. He testified that the family has made more than $1 billion from OxyContin alone. Collectively, the Sacklers are "one of the richest families in the United States, with much of their wealth derived from sales of OxyContin."[96] Their wealth is estimated to be about $13 billion.[97]

234. Board members are intimately involved in the activities of Purdue Pharma Inc. and Purdue Pharma L.P., often on a weekly or even daily basis. Indeed, so complete was their control, that in 2012,

[96] Barry Meier, *Sacklers Directed Efforts to Mislead Public About OxyContin, New Documents Indicate*, N.Y. TIMES, Jan. 15, 2019, *available at* https://www.nytimes.com/2019/01/15/health/sacklers-purdue-oxycontin-opioids.html.
[97] *Id.*

"one Purdue Pharma sales official complained about Richard Sackler's micromanagement of the company's sales and marketing activities."[98]

ii. In 2007, The Directors Decided That Purdue Would Plead Guilty to a Felony, Pay Nearly $700 Million, and Promise Never to Deceive Doctors and Patients Again

235. Purdue's directors and CEOs are liable for Purdue's deadly deception for reasons that go beyond their controlling positions in the companies. They were on notice of Purdue's problems, and obligated to address them, because of their role in previous investigations into Purdue's deception.

236. From 2001 to 2007, Purdue Pharma Inc. and Purdue Pharma L.P. were investigated by 26 states and the U.S. Department of Justice.

237. In 2007, the directors of Purdue Pharma Inc. decided that the Purdue Frederick Company would pay nearly $700 million and plead guilty to a felony crime for misleading doctors and patients about opioids. (The Purdue Frederick Company was another corporate entity controlled by the same people, which shared the same headquarters and facilities as Purdue Pharma L.P.). The company admitted that its supervisors and employees, "with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."

238. The 2007 criminal convictions warned the directors against deception in the strongest terms. Michael Friedman—the CEO of Purdue Pharma Inc., Purdue Pharma L.P., and The Purdue Frederick Company—pleaded guilty to criminal charges that he let Purdue deceive doctors and patients about its opioids. Purdue's top lawyer Howard Udell and Purdue's chief medical officer Paul Goldenheim also pleaded guilty to that same crime.

239. The directors also decided that Purdue Pharma Inc. and Purdue Pharma L.P. would agree to a Consent Judgment in a suit brought by the Commonwealth of Massachusetts in that state. That Judgment ordered that Purdue Pharma Inc. and Purdue Pharma L.P. "shall not make any written or oral claim that is false, misleading, or deceptive" in the promotion or marketing of OxyContin. The Judgment further required that Purdue Pharma Inc. and Purdue Pharma L.P. provide "fair balance" regarding risks and benefits in all promotion of OxyContin—including about the risk of addiction. The Judgment further

[98] *Id.*

required that Purdue Pharma Inc. and Purdue Pharma L.P. establish, implement, and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities. The directors decided that Purdue Pharma Inc. and Purdue Pharma L.P. would agree to that commitment for a 10-year period, from 2007 until 2017.

240. The directors also decided that Purdue Pharma L.P. would agree to a detailed Corporate Integrity Agreement with the U.S. government. The Agreement required Purdue to appoint a Compliance Officer who would "be a member of senior management of Purdue," "make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors," and "be authorized to report on such matters to the Board of Directors at any time."

241. The Corporate Integrity Agreement was built on the idea that the directors would ensure that Purdue never deceived doctors and patients again.

242. The Corporate Integrity Agreement included the directors and CEO as "Covered Persons" from 2007 through 2012. All Covered Persons, including the directors and CEO, were required to comply with rules that prohibit deception about Purdue opioids. The directors and CEO were required to undergo hours of training to ensure that they understood the rules. The directors and CEO were required to report all violations of the rules. The directors and CEO were warned that they could face consequences if they failed to comply with the rules. The directors and CEO certified that they had read and understood the rules and would comply with them.

243. The directors were acutely aware of their obligations under the Corporate Integrity Agreement because, in 2009, Purdue had to report to the Inspector General of the U.S. Department of Health and Human Services that it had not immediately trained a new director on the Agreement. Purdue reported: "a new Director was appointed to Purdue's Board of Directors, without timely notice to either Corporate Compliance or the Office of General Counsel, as otherwise required by policy, resulting in failure to timely launch the training assignment to this new Board member." Purdue assured the U.S. government that it had trained the new director: "Relevant personnel were reminded of existing policy to notify Corporate Compliance and the Office of General Counsel of changes to the Board of Directors. In both instances, these individuals completed their training assignments within 1 day of Corporate

Compliance learning of this issue." Purdue promised the government that the director's training had addressed "the proper methods of promoting, marketing, selling, and disseminating information about Purdue's products," so Purdue would never deceive doctors and patients again.

iii. The Sacklers Repeatedly Refused to Stop the Deception

244. Every year since the 2007 guilty plea, Consent Judgment, and Corporate Integrity Agreement, Purdue's directors and CEO received warning signs about Purdue's ongoing misconduct and opportunities to stop it.

245. In 2008, more Americans died from opioid overdoses than ever before.

246. In 2009, the American Journal of Public Health published an article about Purdue's opioid marketing entitled, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy." The article detailed Purdue's use of sales representatives, targeting of high-prescribers, and deception about addiction. That same year, CDC reported that deaths from opioids had recently tripled.

247. In 2010, Time magazine published a story about Purdue's opioids entitled, "The New Drug Crisis: Addiction by Prescription." It reported on a patient who had become addicted to OxyContin at age 13. Overdoses were the leading cause of accidental death in 15 states. By the spring of 2010, Purdue's directors and CEO had been told that Purdue could not get product liability insurance to cover OxyContin.

248. In 2011, the White House announced that prescription drug abuse was the nation's fastest-growing drug problem and called for "educating healthcare providers about prescription drug abuse … so they will not over-prescribe[.]" The CDC announced that prescription opioid overdoses had reached epidemic levels and called out Purdue's opioids by name. That same year, Fortune magazine interviewed Purdue executives, including Alan Must, who is listed as Vice President of Purdue Pharma Inc. in its official filings. Fortune published a story about Purdue, the Sackler family, and evidence that the company made money off addiction. Mr. Must, the Purdue Vice President, admitted that the company was "well aware" of concerns about its conduct: "We are well aware of detractors. For those individuals who think we're evil … I don't think there's anything we can do that is going to change their opinion."

249. In 2012, the U.S. Senate launched an investigation into whether Purdue was deceiving doctors and patients about opioids. In a letter to the CEO of Purdue Pharma Inc. and Purdue Pharma L.P.,

the Senators warned of "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers." The Senate letter warned Purdue specifically of the danger of patients taking higher doses: "over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks while data suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses." The Senate letter also warned about Purdue misleading doctors and patients: "There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness." The Senate even put the directors and CEO on notice that they specifically were under scrutiny, demanding that Purdue produce to investigators a set of "presentations, reports, and communications to Purdue's management team or board of directors from 2007 to the present."

250. In 2013, the Los Angeles Times revealed that Purdue had been compiling a list for the past decade of 1,800 doctors suspected of recklessly prescribing its opioids, but Purdue had reported only 8% of them to authorities. Purdue attorney Robin Abrams gave multiple interviews to the newspaper. Abrams is listed in official filings as a Vice President of Purdue Pharma Inc., and is the same lawyer who signed Purdue's 2007 settlement agreement. In 2013, she admitted that Purdue had the list, and said Purdue would not agree to disclose it to authorities because she "d[id]n't really want to open up an opportunity for folks come in here and start looking and second-guessing."

251. Abrams and Purdue's directors knew they had reason to fear scrutiny. The state of Kentucky was prosecuting a lawsuit against Purdue for deceiving doctors and patients about opioids. Purdue's lawyers surveyed residents who could be on the jury. One-third knew someone who overdosed or was seriously hurt taking a Purdue opioid, and 29 percent knew someone who died. Purdue itself filed those statistics in court.

252. In 2014, Edward Mahoney, the Executive Vice President, CFO, and Treasurer of Purdue Pharma Inc. stated that the Kentucky lawsuit was so significant that it could "jeopardize Purdue's long-term viability."

253. In 2015, Purdue entered into an agreement with the State of New York to resolve an investigation of its opioid business. The agreement, signed by Abrams (who served as Vice President and

Associate General Counsel for both Purdue Pharma Inc. and Purdue Pharma L.P.), recited New York's findings that Purdue used misleading materials to promote its opioids and aggressively promoted its opioids to high-prescribing doctors who were later arrested for illegal prescribing. That same year, director Richard Sackler was deposed under oath in a suit alleging that Purdue deceived doctors and patients about its opioids.

254. In 2016, the CDC published the CDC Guideline for Prescribing Opioids for Chronic Pain to try to stop dangerous opioid prescribing.

255. In 2017, the President of the United States declared the opioid crisis a national public health emergency.

256. Purdue's CEO and directors knew or should have known about these warnings and many others. Indeed, the 2007 settlement agreement approved by the directors required Purdue to "continue to review news media stories addressing the abuse or diversion of OxyContin and undertake appropriate measures as reasonable under the circumstances to address abuse and diversion so identified." Purdue's records show that the directors and CEO in fact received numerous warnings that Purdue's drugs caused addiction and death.

iv. The Sacklers and Other Corporate Leaders Directed the Deception

257. The directors and CEO knew about, allowed, and directed Purdue's deception. They oversaw Purdue's scheme to send sales representatives to visit doctors thousands of times. They oversaw Purdue's scheme to hire top prescribers to promote its opioids. They oversaw Purdue's effort to get more patients on higher doses of opioids for longer periods.

258. The directors and CEO of Purdue Pharma Inc. controlled Purdue Pharma L.P. The quarterly reports distributed to the directors and CEO of Purdue Pharma Inc. demonstrate that the directors and CEO in fact controlled both Purdue Pharma Inc. and Purdue Pharma L.P. The reports do not distinguish between the companies but instead refer to "Purdue." The reports detail the activities that were undertaken by both companies in the areas "Finance," "Sales & Marketing," "Manufacturing & Supply Chain," "Quality," "Research & Development," "Discovery Research," "Licensing & Business Development," "Corporate Compliance," "External Affairs," "Health Policy," "Human Resources," and

"Information Technology"—all of which were overseen by the directors and CEO of Purdue Pharma Inc. Indeed, the CEO of the two companies was the same.

259. The directors and CEO oversaw Purdue's sales representatives. Director Richard Sackler testified that the sales representatives were the main way that Purdue promoted its opioids. He testified that the key to getting doctors to prescribe and keep prescribing Purdue opioids was regular visits from the sales force. The board tracked the exact number of sales representatives[99] and the exact number of visits they made to urge doctors to prescribe Purdue opioids.[100] The board knew which drugs were promoted;[101] how many visits sales representatives averaged per workday;[102] how much each visit cost Purdue;[103] and the company's plan for sales visits in each upcoming quarter.[104] The Board 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.[105]

260. The directors and CEO oversaw the tactics that sales representatives used to push opioids. A board report analyzed a Purdue initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor to "16.7 minutes in front of the customer."[106]

261. The directors and CEO oversaw promotional claims that representatives presented to doctors during sales visits. They received reports, for example, that a "review of call notes" recorded by Purdue sales representatives "suggested potential comparative claims of superiority of Purdue products

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[99] Specific board reports presenting this information to the directors and CEO were sent in July 2007, April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, November 2012, and July 2013. On information and belief, Purdue produced these particular board reports to the Commonwealth of Massachusetts Attorney General's Office because they include key words used in a document collection search. On information and belief, the Defendants possess additional quarterly reports and related documents, which the Massachusetts Attorney General did not receive.

[100] April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, November 2012, July 2013.

[101] April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, November 2012, July 2013.

[102] April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, November 2012, July 2013.

[103] April 2010, July 2010, October 2010, and January 2011.

[104] April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, November 2012, July 2013.

[105] January 2011.

[106] January 2011.

relative to competitors,"[107] and deceptive promotion of opioids as treatment for "minor pain," including hundreds of examples of deceptive marketing that required "extensive remedial actions."[108]

262. The directors and CEO oversaw Purdue's research, including research that contradicted its marketing. The 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.[109]

263. The directors and the CEO oversaw Purdue's improper response to signs of "abuse and diversion" by high-prescribing doctors. The board was told exactly how many "Reports Of Concern" Purdue sales representatives submitted to the company about doctors they visited to promote opioids (572 Reports Of Concern in the July 2007 board report); how many "field inquiries" Purdue had decided to conduct in response to the reports (21 inquiries in response to 572 Reports Of Concern).[110]

264. The directors and CEO 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.[111]

265. The directors and CEO also oversaw Purdue's strategy to pay high prescribers to promote Purdue opioids. A report for the board listed the exact number of conferences and dinner meetings, with attendance figures, and assured the directors: "We are tracking the prescribing trends of these attendees following the programs and will report the results in future reports."[112] The board was told the amounts paid to certain doctors (for example, that a doctor was paid $29,000 in the first half of 2012), and they received detailed reports on the Return On Investment that Purdue gained from paying doctors to promote its drugs. The board was told that Purdue would allow a "spending limit for gifts" of $750 per doctor per

[107] October 2010.
[108] October 2010.
[109] July 2007.
[110] July 2007.
[111] August 2011.
[112] November 2011.

year;[113] and that the directors should personally report when they gave money, meals, or gifts to doctors to promote Purdue drugs.[114] The board was told explicitly that paying doctors to promote opioids was "a high risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities."[115] When Congress required disclosure of drug company payments to doctors, the board was told there were "significant compliance implications" for Purdue.[116]

266. The directors and CEO also oversaw 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. A report alerted the board that "Net sales of the 40 and 80 mg strengths of OxyContin" had fallen below Purdue's targets in the fall of 2010 and were $85 million below budget.[117] By summer, the board learned that income was $500 million below budget "mainly due to declining sales in 40 mg and 80 mg strengths."[118] By fall, the board reviewed an assessment that Purdue had lost more than $800 million in revenue because patients weren't taking enough 40 mg and 80 mg doses.[119] The board dug into the issue. Multiple reports to the board identified as a "threat" an initiative by public health authorities to save lives by requiring doctors to consult with pain specialists before prescribing opioid doses higher than 80mg/day.[120] The CEO and directors oversaw Purdue's effort to push back against that public health "threat."[121] Executives were pleased to report to the directors in 2013 that "initiatives to validate increased total daily doses are having impact in the field."[122]

267. The directors and CEO also oversaw Purdue's scheme to use higher doses of opioids to keep patients on drugs for longer periods of time. The board received detailed reports of how many patients stayed on Purdue's opioids for long periods (for example, longer than 35 days),[123] along with

[113] July 2007.
[114] July 2013.
[115] August 2011, November 2011.
[116] April 2010.
[117] January 2011.
[118] August 2011.
[119] November 2011.
[120] April 2010, July 2010, October 2010, November 2011.
[121] April 2010, July 2010, October 2010, November 2011.
[122] May 2013 email for board meeting in June 2013.
[123] July 2013.

Purdue's internal research showing that getting patients on higher doses keeps them on the drugs longer[124] — all of which puts patients at greater risk of addiction and death. The board received the confidential results of a study of 57,000 patients that Purdue performed explicitly to determine how opioid dose "influences patient length of therapy."[125] The results showed that patients on the highest doses "are the most persistent." The "Recommended Actions" presented to the board included "additional workshops for the sales force" and "specific direction" to the sales representatives about using higher doses to keep patients on drugs longer. The board was told in writing that encouraging higher doses "is a focal point of our promotion,"[126] and that sales representatives would "emphasize the importance" of increasing patients' opioid doses, as soon as 3 days after starting treatment.[127] The board even tracked specific sales materials, such as "two new patient profiles designed to improve patient identification and titration" – to get more opioid-naïve and elderly patients on higher doses of opioids for longer periods of time.[128] The board was told the exact research behind the sales strategy: higher doses would keep patients on drugs longer because Purdue had found that "83% of patients who discontinued were never titrated to higher doses."[129] The directors and CEO knew or should have known that Purdue's sales strategy was deceptive and that putting patients on opioids at higher doses and for longer periods increased the risk of addiction, overdose, and death.

268. The directors and CEO also oversaw Purdue's strategy of using "savings cards" to get patients on Purdue opioids for longer periods. The board knew how many thousands of cards were used each quarter,[130] how the company calculated the Return On Investment,[131] and that the explicit goal of the program was to hook patients to "remain on therapy longer."[132]

269. The directors and CEO also oversaw Purdue's strategy to target prescribers who did not have special training in opioids (primary care doctors, nurse practitioners, and physician assistants)

[124] July 2013.
[125] November 2012.
[126] November 2012.
[127] November 2012.
[128] July 2013.
[129] July 2013.
[130] November 2012, July 2013.
[131] November 2012.
[132] July 2013.

because they "show the highest responsiveness" to Purdue's sales push.[133] Purdue continued that strategy even though the DEA had expressed concern that Purdue was promoting opioids to clinicians who were not adequately trained in pain management. The directors and CEO also oversaw Purdue's strategy to target elderly patients by promotion "targeted to HCPs that practice in the long term care setting,"[134] even down to the details of advertising that "leverages images of older patients."[135] The directors and CEO knew or should have known that Purdue's sales strategy was deceptive and that targeting primary care doctors and elderly patients increased the risk of addiction, overdose, and death.

270. The directors and CEO also oversaw 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."[136] The board even oversaw Purdue's deceptive websites,[137] and received reports about the specific section that was found to be deceptive by the New York Attorney General.[138]

271. The directors and CEO also oversaw Purdue's response to signs that patients were being harmed. Reports of harm came in by the hundreds and even thousands. One board report explained that "in excess of 5,000 cases with alleged adverse events have already been received and processed by Drug Safety and the Litigation Support group" during a single quarter.[139]

272. Purdue documents show that each of the reports discussed above was sent to every individual Defendant on the board at the time. Specifically, Richard Sackler, Jonathan Sackler, Beverly Sackler, Mortimer Sackler, Kathe Sackler, and Ilene Sackler Lefcourt were sent all the reports discussed above, in July 2007, April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, November 2012, and July 2013.

273. David Sackler was sent the board reports in November 2012 and July 2013.

[133] July 2013.
[134] July 2013.
[135] July 2013.
[136] May 2013 email for board meeting in June 2013.
[137] April 2010, July 2010, October 2010, January 2011.
[138] July 2013.
[139] July 2007.

274. In 2015, Forbes estimates that the Sackler family pulled $700 million from their privately-held companies (including two thirds of that from Purdue). They should have taken precautions to protect patients' health, but they took precautions to protect their own wealth instead.

275. All of the Sacklers knew about and should have known about Purdue's deadly misconduct. Selling opioids was almost all of Purdue's business. Indeed, the sales force was more than half the headcount of the company, and the board directed and oversaw the sales and marketing activities at issue, which were designed to drive patients to higher doses and longer periods on Purdue drugs in order to keep the total kilograms of opioids within Purdue forecasts and to help doctors overcome concerns that increasing length and dose would cause more patient to get addicted and die.

276. The Sackler-dominated board also directed and oversaw public relations campaigns to encourage prescribers to prescribe opioids more aggressively and deceptively dispel their safety and addiction concerns. According to public reports, Richard Sackler, for example, "urged that sales representatives advise doctors to prescribe the highest dosage of [OxyContin] because it as the most profitable."[140]

277. By reason of all the Defendants' unlawful acts, the County of San Mateo has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Damages borne by the County of San Mateo include, for example: (a) costs to treat overdose and addiction, *e.g.*, naloxone, medication-assisted addiction treatment, emergency department, and inpatient and outpatient treatment, including for pregnant women with opioid use disorder and infants suffering from neonatal abstinence syndrome; (b) costs associated with harm reduction, overdose prevention, and education; (c) special costs borne by the County of San Mateo to provide for the public health, safety, and welfare; and (d) loss of productivity and harm to the economy of the County of San Matero, resulting from the epidemic.

2. Janssen

278. Janssen manufactures, markets, sells and distributes the following opioids, each of which are Schedule II drugs, in San Mateo County and nationwide:

[140] Barry Meier, *Sacklers Directed Efforts to Mislead Public About OxyContin, New Documents Indicate*, N.Y. TIMES, Jan. 15, 2019, *available at* https://www.nytimes.com/2019/01/15/health/sacklers-purdue-oxycontin-opioids.html.

Duragesic (fentanyl)	Opioid analgesic delivered via skin patch; contains gel form of fentanyl, a synthetic opioid that is up to 100 times more potent than morphine; delivers fentanyl at regulated rate for up to 72 hours; first approved by the FDA in August 1990.
Nucynta ER (tapentadol hydrochloride)	Opioid agonist; extended-release formulation indicated for severe pain.
Nucynta (tapentadol hydrochloride)	Immediate-release version of tapentadol hydrochloride for the management of moderate to severe acute pain.

According to public records compiled by ProPublica, in 2015 alone Medicare Part D paid more than $8.8 million for claims arising from California physicians' Duragesic, Nucynta ER and Nucynta prescriptions.

279. Janssen introduced Duragesic in 1990. It is indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Janssen also markets Nucynta, which was first approved by the FDA in 2008, formulated as both a tablet and an oral solution and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older." Additionally, Janssen markets Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the "management of . . . pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." This pain indication was later altered to "management of moderate to severe chronic pain in adults" and "neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." Janssen sold Nucynta and Nucynta ER to Depomed in 2015 for $1.05 billion.

a. The FDA Warned Janssen Regarding Its False Messaging

280. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of "homemade" promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq.* In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain

misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."

281. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse:

- You present the claim, "Low abuse potential!" This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, "Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine." Therefore, this claim is false or misleading.[141]

282. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence." Specifically, the FDA stated that Janssen was marketing Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

- You present the claim, "It's not just for end stage cancer anymore!" This claim suggests that Duragesic can be used for any type of pain management. However, the PI for Duragesic states, "Duragesic (fentanyl transdermal system) is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means . . . ." Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states, BECAUSE SERIOUS OR LIFE-THREATENING HYPO VENTILATION

[141] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica, at 2 (Mar. 30, 2000).

> COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED:
>
> - In the management [of] acute or post-operative pain, including use in out-patient surgeries . . . .'"

283. The March 30, 2000 letter also stated Janssen failed to adequately present "contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product":

> Although this piece contains numerous claims for the efficacy and safety of Duragesic, ***you have not presented any risk information*** concerning the boxed warnings, contraindications, warnings, precautions, or side effects associated with Duragesic's use . . . . Therefore, this promotional piece is lacking in fair balance, or otherwise misleading, because it fails to address important risks and restrictions associated with Duragesic therapy.

284. **On September 2, 2004,** the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products."

285. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. The letter stated that the claim was false or misleading because the claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN:

> The file card presents the prominent claim, "Low reported rate of mentions in DAWN data," along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid products, including Hydrocodone/combinations (21,567 mentions), Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The file card thus suggests that Duragesic is less abused than other opioid drugs.

> This is false or misleading for two reasons. First, we are not aware of substantial evidence or substantial clinical experience to support this comparative claim. The DAWN data cannot provide the basis for a valid comparison among these products. As you know, DAWN is not a clinical trial database. Instead, it is a national public health surveillance system that monitors drug-related emergency department visits and deaths. If you have other data demonstrating that Duragesic is less abused, please submit them.
>
> Second, Duragesic is not as widely prescribed as other opioid products. As a result, the relatively lower number of mentions could be attributed to the lower **frequency of use, and not to a lower incidence of abuse. The file card fails to disclose this information.[1]"**[142]

286. The September 2, 2004 letter also detailed a series of unsubstantiated, false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including that:

- **"Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep."**
- **"All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain."**
- **Significantly reduced nighttime awakenings."**
- **"Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index."**
- **"Significant improvement in physical functioning summary score."**
- **"Significant improvement in social functioning."**

287. In addition, the September 2, 2004 letter identified "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include '1,360 [lives] . . . and counting," [w]ork, uninterrupted," [l]ife, uninterrupted," [g]ame, uninterrupted," [c]hronic pain relief that supports functionality,' [h]elps patients think less about their pain,' and [i]mprove[s] . . . physical and social functioning.' The September 2, 2004 letter stated: "Janssen has not provided references to support these

[142] Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc., at 2 (Sept. 2, 2004).

outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."

288. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

b. Janssen Funded False Publications and Presentations

289. Despite these repeated warnings, Janssen continued to falsely market the risks of opioids. In 2009, PriCara, a "Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.," sponsored a 2009 brochure, "Finding Relief: Pain Management for Older Adults," aimed at potential patients. The brochure included a free DVD featuring actress Kathy Baker, who played a doctor in the popular television series "Picket Fences."

290. The brochure represented that it was a source for older adults to gain accurate information about treatment options for effective pain relief:

> This program is aimed specifically at older adults and what they need to know to get effective pain relief. You will learn that there are many pathways to this relief. You will learn about your options for pain management and how to find the treatment that's right for you. By learning more about pain and the many ways it can be treated, you are taking solid steps toward reducing the pain you or a loved one may be feeling.[143]

291. Despite representing itself as a source of accurate information, the brochure included false and misleading information about opioids, including a section seeking to dispel purported "myths" about opioid usage:

Opioid Myths

Myth: Opioid medications are always addictive.

[143] Molly Huff, *Finding Relief: Pain Management for Older Adults*, CENTERS FOR PAIN MANAGEMENT (Mar. 9, 2011), available at http://www.managepaintoday.com/news/-Finding-Relief-Pain-Management-for-Older-Adults (Last Accessed June 7, 2018).

> **Fact:** Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.
>
> **Myth:** Opioids make it harder to function normally.
>
> **Fact:** When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.
>
> **Myth:** Opioid doses have to get bigger over time because the body gets used to them.
>
> **Fact:** Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increase[s] over time.

292. Among the "Partners" listed in "Finding Relief: Pain Management for Older Adults" are the AAPM, the AGS and the AGS Foundation for Health in Aging. Janssen (along with Purdue and Endo) funded the AAPM. The AGS and the AGS Foundation for Health in Aging published a pain guide titled "Finding Relief: Pain Management for Older Adults," which was funded by Janssen.

293. In addition, Janssen disseminated false information about opioids on the website Prescribe Responsibly, which remains publicly accessible at www.prescriberesponsibly.com. According to the website's legal notice, all content on the site "is owned or controlled by Janssen."[144] The website includes numerous false or misleading representations concerning the relative safety of opioids and omissions of the risks associated with taking them. For example, it states that while practitioners are often concerned about prescribing opioids due to "questions of addiction," such concerns "are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid . . . analgesic therapy."[145]

294. Prescribe Responsibly also compared the risks of opioid use favorably to those associated with NSAIDs, such as aspirin and ibuprofen, and stated that many patients develop tolerance for opioid side effects:

> Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true "ceiling dose" for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual

[144] *Legal Notice*, PRESCRIBE RESPONSIBLY (2015), available at http://www.prescriberesponsibly.com/legal-notice (Last Accessed June 7, 2018).

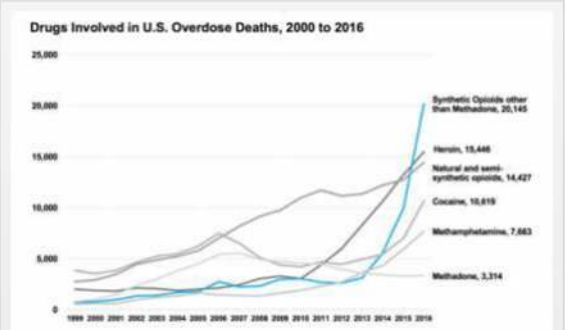
[145] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, PRESCRIBE RESPONSIBLY, available at https://www.prescriberesponsibly.com/articles/opioid-pain-management (Last Accessed June 7, 2018).

interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.

295. Further, Prescribe Responsibly repeats the scientifically unsupported discussion of "pseudoaddiction" as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases."[146] Thus, pseudoaddiction is defined as a condition requiring the prescription of more or stronger opioids.

296. Janssen also made thousands of payments to physicians nationwide, including to San Mateo County physicians, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

297. As people became more and more hooked on prescription pain killers, they moved to heroin, and increasingly to fentanyl, which is even more potent and cheaper than heroin, and which as set forth above was being deceptively marketed by Janssen, causing a dramatic spike in heroin and fentanyl overdose deaths:



Drugs Involved in U.S. Overdose Deaths* - Among the more than 64,000 drug overdose deaths estimated in 2016, the sharpest increase occurred among deaths related to fentanyl and fentanyl analogs (synthetic opioids) with over 20,000 overdose deaths. Source: CDC WONDER

c. Janssen Failed to Report Suspicious Sales as Required

298. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include

[146] Howard A. Heit, M.D. & Douglas L. Gourlay, M.D., *What a Prescriber Should Know Before Writing the First Prescription*, PRESCRIBE RESPONSIBLY (2015), http://www.prescriberesponsibly.com/articles/before-prescribing-opioids (Last Accessed June 7, 2018).

orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b). The CSA's requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o).

299. Janssen is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

300. The California Code of Regulations requires all drug manufacturers and wholesalers to report "all sales of dangerous drugs subject to abuse" to the Board up to 12 times per year, pursuant to the Board's request. 16 C.C.R. §1782.

301. Janssen failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Janssen also failed to report to the Board sales of dangerous drugs subject to abuse. Janssen's failure to timely report these and other suspicious sales violated the CSA and California law

3. Endo

302. Endo manufactures, markets, sells and distributes the following opioids, all of which are Schedule II drugs, in San Mateo County and nationwide:

Opana ER (oxymorphone hydrochloride)	**Opioid agonist; extended-release tablet formulation; first drug in which oxymorphone is available in an oral, extended-release formulation: first approve in 2006.**
Opana (oxymorphone hydrochloride)	**Opioid agonist; first approved in 2006.**
Percodan (oxymorphone hydrochloride and aspirin)	**Branded tablet combining oxymorphone hydrochloride and aspirin; first approved in 1950; first marketed by Endo in 2004.**
Percocet (oxymorphone hydrochloride and	**Branded tablet that combines oxymorphone hydrochloride and acetaminophen; first approved in 1999; first marketed by Endo in 2006.**
Oxycodone	**Generic product.**
Oxymorphone	**Generic product.**
Hydromorphone	**Generic product.**
Hydrocodone	**Generic product.**

303. According to public records compiled by ProPublica, in 2015 alone Medicare Part D paid more than $10.96 million for claims arising from California physicians' Opana ER and Percocet prescriptions.

304. The FDA first approved an injectable form of Opana in 1959. The injectable form of Opana was indicated "for the relief of moderate to severe pain" and "for preoperative medication, for support of anesthesia, for obstetrical analgesia, and for relief of anxiety in patients with dyspnea associated with pulmonary edema secondary to acute left ventricular dysfunction." However, oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.[147]

305. In 2006, the FDA approved a tablet form of Opana in 5 mg and 10 mg strengths. The tablet form was "indicated for the relief of moderate to severe acute pain where the use of an opioid is appropriate." Also in 2006, the FDA approved Opana ER, an extended-release tablet version of Opana available in 5 mg, 10 mg, 20 mg and 40 mg tablet strengths. Opana ER was indicated "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Endo's goal was to use Opana ER to take market share away from OxyContin; thus it was marketed as being safer, with less abuse potential than OxyContin because of its crush-resistance.

306. According to Endo's annual reports, sales of Opana and Opana ER regularly generate several hundred million dollars in annual revenue for the company, growing from $107 million in 2007 to as high as $384 million in 2011. Over the last ten years, Percocet has generated an average of well over $100 million in annual revenue for the company.

a. Endo Falsely Marketed Opana ER as Crush Resistant

307. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo claimed offered "safety advantages" over the original formulation because the reformulation "is resistant to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less likely to be chewed or crushed even in situations where there is no intent for abuse, such as where patients inadvertently chew the tablets, or where caregivers attempt to crush the tablets for easier administration with food or by gastric tubes, or where children accidentally gain access to the tablets."

[147] John Fauber & Kristina Fiore, *Opana gets FDA approval despite history of abuse, limited effectiveness in trials*, MILWAUKEE JOURNAL SENTINEL (May 9, 2015), archive available at http://archive.jsonline.com/%20watchdog/watchdogreports/opana-gets-fda-approval-despite-histoty-of-abuse-limited-effectiveness-in-trials-b99494132z1-303198321.html (Last Accessed June 7, 2018).

308. Endo publicized the reformulated version of Opana ER as "crush-resistant." To combat the fear of opioids, sales representatives touted it to doctors as a safer option due to its crush-resistance and extended release. In a December 12, 2011 press release announcing FDA approval of the reformulated Opana ER, Endo's executive vice president for research and development and chief scientific officer highlighted the reformulated version's safety characteristics:

> **"FDA's approval of this new formulation of Opana ER is an important milestone for both the Long Acting Opioid category as well as Endo's branded pharmaceutical portfolio. . . . Patient safety is our top concern and addressing appropriate use of opioids is a responsibility that we take very seriously. We firmly believe this 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."**

309. However, in October 2012, the CDC issued a health alert noting that 15 people in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana ER. In response, Endo's chief scientific officer stated that, while Endo was looking into the data, he was not especially concerned: "Clearly, we are looking into this data, . . . but it's in a very, very distinct area of the country."[148]

310. Shortly thereafter, the FDA determined that Endo's conclusions about the purported safety advantages of the reformulated Opana ER were unfounded. In a May 10, 2013 letter to Endo, the FDA found that the tablet was still vulnerable to "cutting, grinding, or chewing," "can be prepared for insufflation (snorting) using commonly available tools and methods," and "can [be readily] prepared for injection." It also warned that preliminary data suggested "the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation."

311. A 2014 study co-authored by an Endo medical director corroborated the FDA's warning. This 2014 study found that while overall abuse of Opana had fallen following Opana ER's reformulation, it also found that injection had become the preferred way of abusing the drug. However, the study reassured that it was not possible to draw a causal link between the reformulation and injection abuse.

[148] Tom Dreisbach, *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, NPR (Apr. 1, 2016), available at https://www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak (Last Accessed June 7, 2018).

312. The study's failure to adequately warn healthcare providers and the public was catastrophic. On April 24, 2015, the CDC issued a health advisory concerning its investigation of "a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs."[149] The CDC specifically attributed the outbreak to the injection of Opana ER. As the advisory explained:

> From November 2014 to January 2015, ISDH identified 11 new HIV infections in a rural southeastern county where fewer than 5 infections have been identified annually in the past. As of April 21, 2015, an on-going investigation by ISDH with assistance from CDC has identified 135 persons with newly diagnosed HIV infections in a community of 4,200 people; 84% were also HCV infected. Among 112 persons interviewed thus far, 108 (96%) injected drugs; all reported dissolving and injecting tablets of the prescription-type opioid oxymorphone (OPANA® ER) using shared drug preparation and injection equipment.'"

b. New York's Investigation Found Endo Falsely Marketed Opana ER

313. On February 18, 2017, the State of New York announced a settlement with Endo requiring it "to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER." In the Assurance of Discontinuance that effectuated the settlement, the State of New York revealed evidence showing that Endo had known about the risks arising from the reformulated Opana ER even before it received FDA approval.

314. Among other things, the investigation concluded that:

- ***Endo improperly marketed Opana ER as designed to be crush resistant, when Endo's own studies dating from 2009 and 2010 showed that the pill could be crushed and ground;***
- ***Endo improperly instructed its sales representatives to diminish and distort the risks associated with Opana ER, including the serious danger of addiction;*** and
- ***Endo made unsupported claims comparing Opana ER to other opioids and failed to disclose accurate information regarding studies addressing the negative effects of Opana ER.***
- **In October 2011, Endo's director of project management e-mailed the company that had developed the formulation technology for reformulated**

[149] *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs*, CDC (Apr. 24, 2015), available at https://emergency.cdc.gov/han/han00377.asp (Last Accessed June 7, 2018).

> **Opana ER to say there was little or no difference between the new formulation and the earlier formulation, which Endo withdrew due to risks associated with grinding and chewing:**
>
> ***"We already demonstrated that there was little difference between [the original and new formulations of Opana in Study 108 when both products were ground. FDA deemed that there was no difference*** **and this contributed to their statement that we had not shown an incremental benefit.** ***The chewing study (109) showed the same thing no real difference*** **which the FDA used to claim no incremental benefit."[150]**

315. Endo conducted two additional studies to test the reformulated Opana ER's crush resistance. Study 901 tested whether it was more difficult to extract reformulated Opana ER than the original version, and whether it would take longer to extract from reformulated Opana ER than from the original version. The test revealed that both formulations behaved similarly with respect to manipulation time and produced equivalent opioid yields.

316. The settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that "[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant." The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.

317. Regardless, pamphlets produced by Endo and distributed to physicians misleadingly marketed the reformulated Opana ER as "'designed to be crush resistant," and Endo's sales representative training identified Opana ER as "CR," short for crush resistant.

318. The Office of the Attorney General of New York also revealed that the "managed care dossier" Endo provided to formulary committees of healthcare plans and pharmacy benefit managers misrepresented the studies that had been conducted on Opana ER. The dossier was distributed in order to assure the inclusion of reformulated Opana ER in their formularies.

319. According to Endo's vice president for pharmacovigilance and risk management, the dossier was presented as a complete compendium of all research on the drug. However, it

[150] In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc., Assurance No. 15-228, *Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15*, at 5 (Mar. 1, 2016), available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (Last Accessed June 7, 2018).

omitted certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

320. The settlement also detailed Endo's false and misleading representations about the non-addictiveness of opioids and Opana. Until April 2012, Endo's website for the drug, www.opana.com, contained the following representation: "Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

321. The Office of the Attorney General of New York also disclosed that training materials provided by Endo to sales representatives stated: "Symptoms of withdrawal do not indicate addiction." This representation is inconsistent with the diagnosis of opioid-use disorder as provided in the Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition).

322. The Office of the Attorney General of New York also found that Endo trained its sales representatives to falsely distinguish addiction from "pseudoaddiction," which it defined as a condition in which patients exhibit drug-seeking behavior that resembles but is not the same as addiction. However, Endo's vice president for pharmacovigilance and risk management testified that he was not aware of any research validating the concept of pseudoaddiction.

c. Endo Funded False Publications and Presentations

323. Like several of the other Manufacturer Defendants, Endo provided substantial funding to purportedly neutral medical organizations, including APF.

324. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in *Pain Medicine News,* titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[151]

[151] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, PAIN MED. NEWS, available at https://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf (Last Accessed June 7, 2018).

325. The article commenced with the observation that "[a]n estimated 50 to 60 million people . . . suffer from chronic pain." It continued:

> 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.

326. 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. It concluded by saying that "use of opioids may be effective in the management of chronic pain."

327. Later, in 2014, Endo issued a patient brochure titled "Understanding Your Pain Taking Oral Opioid Analgesics." It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

328. The brochure included numerous false and misleading statements minimizing the dangers associated with prescription opioid use. Among other things, the brochure falsely and misleadingly represented that:

> Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.
>
> * * *
>
> *How can I be sure I'm not addicted?*
>
> - Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.

- Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons — to relieve your pain and improve your function. You are not addicted.
- Your doctor or nurse may instruct you to do some of the following:
- Take the next dose before the last dose wears off. If pain is present most of the day and night, the pain medicine may be taken at regularly scheduled times. If you are taking a short-acting opioid, this usually means taking it every 4 hours. You may need to set your alarm, especially at night, to be sure you take your dose before the pain returns and wakes you up.
- If your pain comes and goes, take your pain medicine when pain first begins, before it becomes severe.
- If you are taking a long-acting opioid, you may only need to take it every 8 to 12 hours, but you may also need to take a short-acting opioid in between for any increase in pain.[152]

329. In 2008, Endo also provided an "educational grant" to PainEDU.org, which produced a document titled "Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q." Endo and King Pharmaceuticals sponsor PainEDU.org.[153] SOAPP describes itself "as a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require." It falsely highlights purportedly "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."

330. Endo also sponsored the now-defunct website painknowledge.com, which was created by APF and stated it was "a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches." Among

[152] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, ENDO PHARMACEUTICALS (2004), available at http://www.thblack.com/links/rsd/Understand_Pain_Opioid_Analgesics.pdf (Last Accessed June 7, 2018) (emphasis in original).

[153] B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium*, PAIN EDUCATORS (2009), available at https://www.paineducators.org/wp-content/uploads/2012/12/ASPE-ResForEducationOnPainAn.pdf (Last Accessed June 7, 2018).

other featured content, painknowledge.com included a flyer titled "Pain: Opioid Therapy," which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence and addiction.

331. Endo, along with Janssen and Purdue, also provided grants to APF to distribute Exit Wounds, discussed above. *See supra* ¶¶ 126-127.[154]

332. Endo also made thousands of payments to physicians nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

d. The FDA Requested Endo Withdraw Opana ER Due to the Public Health Consequences of Abuse

333. On June 8, 2017, the FDA asked Endo to remove reformulated Opana ER from the market "based on its concern that the benefits of the drug may no longer outweigh its risks."[155] According to the FDA's press release, it sought voluntary removal "due to the public health consequences of abuse."[156] The decision to seek Opana ER's removal from sale followed a March 2017 FDA advisory committee meeting, during which a group of independent experts voted 18-8 that the drug's benefits no longer outweigh the risks associated with its use. According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, the risks include "several serious problems," including "outbreaks of HIV and Hepatitis C from sharing the drug after it was extracted by abusers" and "a[n] outbreak of serious blood disorder."[157] If Endo did not comply with the request, Dr. Woodcock stated that the FDA would

[154] Iraq War Veteran Amputee, *Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, VETERANS OF MODERN WARFARE (Nov. 25, 2009), archive available at http://vmwusa.org/index.php/news/vmwarch/62-vmwnow/vmwnow/504-exitwounds (Last Accessed June 8, 2018).

[155] *FDA requests removal of Opana ER for risks related to abuse*, FDA (June 8, 2017), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm (Last Accessed June 7, 2018).

[156] *Id.*

[157] *Id.*

issue notice of a hearing and commence proceedings to compel its removal. On July 6, 2017, Endo pulled Opana ER from the U.S. market.[158]

e. Endo Failed to Report Suspicious Sales as Required

334. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b). The CSA's requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o).

335. Endo is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

336. The California Code of Regulations requires all drug manufacturers and wholesalers to report "all sales of dangerous drugs subject to abuse" to the Board up to 12 times per year, pursuant to the Board's request. 16 C.C.R. §1782.

337. Endo failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Endo also failed to report to the Board sales of suspicious drugs subject to abuse. Endo's failure to timely report these and other suspicious sales violated the CSA and California law.

4. Cephalon

338. Cephalon manufactures, markets, sells and distributes the following opioids, all of which are Schedule II drugs, in San Mateo County and nationwide:

[158] Linda A. Johnson, *Painkiller Maker Stops Sales at FDA Request Because of Abuse*, US NEWS (July 6, 2017), available at https://www.usnews.com/news/business/articles/2017-07-06/painkiller-maker-stops-sales-at-fda-request-because-of-abuse (Last Accessed June 7, 2018).

Actiq (fentanyl citrate)	Opioid analgesic; oral transmucosal lozenge; indicated only for the management of breakthrough pain (or "BTP") in cancer patients — pain that for a short time "breaks through" medication that otherwise effectively controls a patient's persistent pain — in patients 16 and older with malignancies; commonly referred to as a lollipop because designed to look and perform like one; annroved in 1998 with restricted distribution program.
Fentora (fentanyl buccal)	Rapid-release tablet for BTP in cancer patients who are already receiving and tolerant of around-the-clock Opioid therapy: approved 2006.
Generic of OxyContin (oxycodone hydrochloride)	Opiate agonist.

According to public records compiled by ProPublica, in 2015 alone Medicare Part D paid $3.77 million for claims arising from California physicians' Fentora prescriptions.

339. Actiq is designed to resemble a lollipop and is meant to be sucked on at the onset of intense BTP in cancer patients. It delivers fentanyl citrate, a powerful opioid agonist that is 80 times stronger than morphine,[159] rapidly into a patient's bloodstream through the oral membranes. Actiq would later become part of a category of opioids now known as transmucosal immediate-release fentanyl ("TIRF") products. "Transmucosal" refers to the means through which the opioid is delivered into a patient's bloodstream, across mucous membranes, such as inside the cheek, under the tongue or in the nose. Because it is absorbed through those membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.[160]

340. Understanding the risks of introducing such an intense opioid analgesic to the market, the FDA provided approval of Actiq in November 1998 for only a narrow group of people: ***"ONLY*** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[161] Further, the FDA

[159] John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, WALL ST. J. (Nov. 3, 2006), available at https://www.opiates.com/narcotic-lollipop-becomes-big-seller-despite-fda-curbs/ (Last Accessed June 7, 2018).

[160] *Cephalon, Inc.*, COMPANY HISTORIES, available at http://www.company-histories.com/Cephalon-Inc-Company-History.html (Last Accessed June 7, 2018).

[161] NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and Research, to Patricia J. Richards, Anesta Corporation (1998); *see also Actiq*, CENTERWATCH (2018),

explicitly stated that Actiq ***"must not*** be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could be deadly to children and was "intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."

341. The FDA also required that Actiq be provided only in compliance with a strict risk-management program that explicitly limited the drug's direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.

342. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States.

343. Cephalon purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell this faster-acting version of Actiq; but once again, concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the- clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

a. Cephalon Falsely and Aggressively Marketed Cancer Drug Actiq to Non-Cancer Treating Physicians

344. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a broader audience and thus began marketing its lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer pain, targeting non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

available at https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/495/actiq (Last Accessed June 8, 2018).

345. According to "[d]ata gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits to non-oncologists to pitch Actiq increased six-fold between 2002 and 2005. Cephalon representatives would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each of which was good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer patients.

346. Cephalon's efforts paid off. In 2000, Actiq generated $15 million in sales. By 2002, it attributed a 92% increase in Actiq sales to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[162] By 2005, Actiq's sales total had jumped to $412 million, making it, a drug approved for only a narrow customer base, Cephalon's second-best selling drug. By the end of 2006, Actiq's annual sales had exceeded $500 million.

347. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. Results of the ImpactRx Survey suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."

b. Government Investigations Found Cephalon Falsely Marketed Actiq for Off-Label Uses

348. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of MIS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses. Specifically, the DOJ stated:

> From 2001 through at least 2006, ***Cephalon was allegedly promoting Actiq for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also***

[162] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003).

> ***promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results.***

349. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon's unlawful practices:

> ***"This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line.*** People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."[163]

350. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;
- Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches;
- Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use;
- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication;

[163] *Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing*, DOJ (Sept. 29, 2008), available at https://www.justice.gov/sites/default/files/civil/legacy/2014/01/09/Cephalon%20Press%20Release.pdf (Last Accessed June 7, 2018).

- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and
- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.[164]

351. Still, the letters, the FDA's safety alert, DOJ and state investigations and the massive settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

c. Cephalon Falsely and Aggressively Marketed Cancer Drug Fentora to Non-Cancer Treating Physicians

352. From the time it first introduced Fentora to the market in October 2006, Cephalon targeted non-cancer doctors, falsely represented Fentora as a safe, effective off-label treatment for non-cancer pain and continued its disinformation campaign about the safety and non-addictiveness of Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

353. During an investor earnings call shortly after Fentora's launch, Cephalon's chief executive officer ("CEO") described the "opportunity" presented by the use of Fentora for non-cancer pain:

> ***The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain.***
>
> * * *
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and well being and the exciting growth potential that it has for Cephalon.

[164] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, WALL ST. J. (Nov. 21, 2006) at B1.

> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much biger field force presence, the opportunity that FENTORA represents is enormous.[165]

d. The FDA Warned Cephalon Regarding its False and Off-Label Marketing of Fentora

354. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain."[166]

355. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.[167] An FDA advisory committee lamented that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

356. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

357. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this

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[165] *Cephalon Q1 2007 Earnings Call Transcript*, SEEKING ALPHA (May 1, 2007), available at https://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript (Last Accessed June 7, 2018).

[166] *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)*, FDA (Sept. 26, 2007).

[167] *FENTORA (fentanyl buccal tablet) CII*, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisor Committee, FDA (May 6, 2008).

is not the case." Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

358. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

359. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy Times* titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."[168]

e. Cephalon Funded False Publications and Presentations

360. In addition to its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids — disseminating the unproven and deceptive messages that opioids were safe for the treatment of chronic, long-term pain, that they were non-addictive and that they were woefully under-prescribed to the detriment of patients who were needlessly suffering. It did so by sponsoring pro-opioid front groups, misleading prescription guidelines, articles and CME programs, and it paid physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

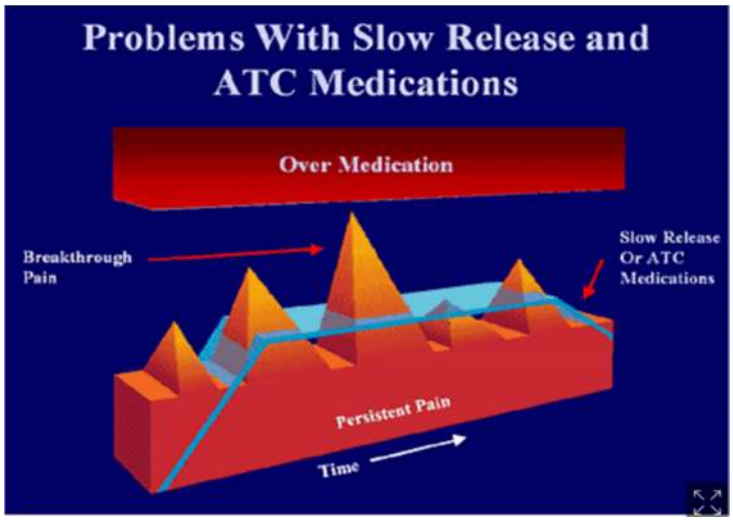
361. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians in San Mateo County and across the country.

362. For example, a 2003 Cephalon-sponsored CME presentation titled "Pharmacologic Management of Breakthrough or Incident Pain," posted on Medscape in February 2003, teaches:

[168] *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*, PHARMACY TIMES (Jan. 13, 2012), available at https://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems (Last Accessed June 7, 2018).

> ***[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[169]***

363. Another Cephalon-sponsored CME presentation titled "Breakthrough Pain: Treatment Rationale with Opioids" was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[170] The doctor lists fentanyl as one of the most effective opioids available for treating BTP, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned.



364. Dr. Stephen H. Landy ("Landy") authored a 2004 CME manuscript available on Medscape titled "Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache

[169] Michael J. Brennan, *et al*., *Pharmacologic Management of Breakthrough or Incident Pain*, MEDSCAPE, available at https://www.medscape.org/viewarticle/449803_9 (Last Accessed June 7, 2018).

[170] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, MEDSCAPE, available at https://www.medscape.org/viewarticle/461612 (Last Accessed June 7, 2018).

Pain In Outpatients: A Case Series." The manuscript preparation was supported by Cephalon. Landy describes the findings of a study of fentanyl citrate for the use of migraine headache pain and concluded that "OTFC rapidly and significantly relieved acute, refractory migraine pain in outpatients . . . and was associated with high patient satisfaction ratings."[171] Based on an analysis of publicly available data, Cephalon paid Landy approximately $190,000 in 2009-2010 alone, and in 2015-2016, Cephalon paid Landy another $75,000.

365. In 2006, Cephalon sponsored a review of scientific literature to create additional fentanyl-specific dosing guidelines titled "Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC®) Dosing Guidelines."[172] The article purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain and produce dosing guidelines in both cancer and non-cancer patients. In pertinent part, it states.

> Oral transmucosal fentanyl citrate has a proven benefit in treating cancer-associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food and Drug Administration (FDA)-approved indication for Actiq. ***Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients.***

366. Deeper into the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing ***"There is no evidence that opioid safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain."*** Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

> Alternatively, ***OTFC might also be used cautiously and safely for*** acute pain experienced by ***patients who are not opioid tolerant. Parenteral opioids are routinely used for acute pain in patients who are not opioid tolerant.*** Examples include episodic pain *(i.e.,* refractory migraine pain, recurrent renal calculi, etc.) and acute pain that follows surgery, trauma, or painful procedures (burn dressing change, bone marrow aspiration, lumbar puncture). Assuming that clinical experience with IV morphine in patients who are not opioid tolerant can be extrapolated, OTFC should be safe and efficacious in such settings as wel1.

[171] Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series*, 44(8) HEADACHE 762-6 (2004), available at https://www.ncbi.nlm.nih.gov/pubmed/15330821 (Last Accessed June 7, 2018).

[172] Gerald M. Aronoff, *et al*., *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6(4) PAIN MED. 305-14 (2005), available at https://academic.oup.com/painmedicine/article/6/4/305/1887629 (Last Accessed June 7, 2018).

367. Through its sponsorship of FSMB *(see supra* ¶¶ 111-113), Cephalon continued to encourage the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients' displays of traditional drug-seeking behaviors as merely "pseudoaddiction."

368. Cephalon also disseminated its false messaging through speakers' bureaus and publications. For example, 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 (BTP), 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 FEBT is safe and well-tolerated in patients with chronic pain and BTP."

369. Cephalon sponsored another CME presentation written by Webster and M. Beth Dove titled "Optimizing Opioid Treatment for Breakthrough Pain" and offered on Medscape from September 28, 2007 through December 15, 2008. The presentation teaches that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.[173]

370. Fine authored a Cephalon-sponsored CME presentation titled "Opioid-Based Management of Persistent and Breakthrough Pain," with Drs. Christine A. Miaskowski and Michael J. Brennan. Cephalon paid to have this CME presentation published as a "Special Report " supplement of the journal *Pain Medicine News* in 2009.[174] The CME presentation targeted a wide variety of non-oncologist healthcare providers who treat patients with chronic pain with the objective of educating "health care professionals about a semi-structured approach to the opioid-based management of persistent and

[173] Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, MEDSCAPE, available at https://www.medscape.org/viewarticle/563417 (Last Accessed June 7, 2018).

[174] Perry G. Fine, et al., *Long-Term Safety And Tolerability Of Fentanyl Buccal Tablet For The Treatment Of Breakthrough Pain In Opioid-Tolerant Patients With Chronic Pain: An 18-Month Study*, 40(5) J. PAIN SYMPTOM MGMT. 747-60 (2010) (hereinafter Fine, "*Long-Term Safety*").

breakthrough pain," including the use of fentanyl. The CME presentation purports to analyze the "combination of evidence- and case-based discussions" and ultimately concludes:

> Chronic pain is a debilitating biopsychosocial condition prevalent in both cancer and noncancer pain populations. . . . Opioids have an established role in pain related to cancer and other advanced medical illnesses, as well as an increasing contribution to the long-term treatment of carefully selected and monitored patients with certain [chronic noncancer pain] conditions. ***All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial or opioid therapy, although not all of them will be selected.***

371. Along with Purdue, Cephalon sponsored APF's guide *(see supra* ¶ 122-124), which warned against the purported under-prescribing of opioids, taught that addiction is *rare* and suggested that opioids have *"no ceiling dose"* and are therefore the most appropriate treatment for severe pain.

372. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continues:

> ***Pain management is a fundamental human right*** in all patients not only with acute postoperative pain but **also *in patients suffering from chronic pain***. Treating the underlying cause of pain does not usually treat all of the ongoing pain. Minimal pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain is only recently being explored as a complex condition that requires individual treatment and a multidisciplinary approach. It is considered to be a disease entity.[175]

373. Cephalon was one of several opioid manufacturers who collectively paid 14 of the 21 panel members who drafted the 2009 APS-AAPM opioid treatment guidelines.[176]

374. In the March 2007 article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[177] published in the nationally circulated journal *Pain Medicine,* physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of

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[175] Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) ADVANCES IN PAIN MANAGEMENT 50-52 (2008).

[176] Roger Chou, *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) JOURNAL OF PAIN 113-130 (2009).

[177] Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) PAIN MED. 281-88 (2007), available at https://academic.oup.com/painmedicine/article/8/3/281/1829094 (Last Accessed June 7, 2018).

BTP to the chronic, non-cancer setting. The authors stated that the "OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients." The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with ***chronic noncancer pain*** and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP ***and the potential benefits of BTP-specific therapy*** suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.

375. Cephalon also sponsored, through an educational grant, the regularly published journal *Advances in Pain Management.* In a single 2008 issue of the journal, there are numerous articles from Portenoy, Dr. Steven Passik ("Passik"), Dr. Kenneth L. Kirsh ("Kirsh") and Webster, all advancing the safety and efficacy of opioids. In an article titled "Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients," Webster expresses disdain for the prior 20 years of opioid phobia.

376. In another article from the same issue, "Appropriate Prescribing of Opioids and Associated Risk Minimization," Passik and Kirsh state: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function" and that then-recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[178]

377. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study." In that article, Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here

[178] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) ADVANCES IN PAIN MANAGEMENT 9-16 (2008).

has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."

378. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable manageable, and tolerable." They also conclude that the number of abuse-related events was "small."

379. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy and others.

380. Cephalon's payments to doctors have resulted in studies that support its sales but, on closer examination, are biased or irreparably flawed. For instance, and upon information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group whatsoever. A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of **BTP** in cancer patients noted that clinical trials to date used varying criteria, that "the approaches taken . . . [did] not uniformly reflect clinical practice" and that "the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias."[179]

381. Teva, which acquired Cephalon, has repeatedly refused to produce information requested as part of a U.S. Senate investigation into opioid manufacturers and distributors. Senator McCaskill issued requests on July 26, 2017 and September 28, 2017. In a letter to Teva sent September 28, 2017, Senator McCaskill explained that "the company's decision to obstruct basic oversight on the opioid epidemic should deeply concern shareholders." On March 6, 2018, Senator McCaskill issued a press release castigating Teva

[179] Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, (6) Patient Preference and Adherence 465-7 (2012), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393121/ (Last Accessed June 7, 2018).

for its continued refusal to comply with her requests: "Teva's refusal to cooperate with Congressional requests strongly suggests they have something to hide."[180]

f. Cephalon Failed to Report Suspicious Sales as Required

382. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b). The CSA's requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o).

383. Cephalon is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule H controlled substances to register with the DEA.

384. The California Code of Regulations requires all drug manufacturers and wholesalers to report "all sales of dangerous drugs subject to abuse" to the Board up to 12 times per year, pursuant to the Board's request. 16 C.C.R. §1782.

385. Cephalon failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Cephalon's failure to timely report these and other suspicious sales violated the CSA and California law.

5. Insys

386. Insys manufactures, markets, sells and distributes the following pharmaceutical Schedule II drug in San Mateo County and nationwide:

Subsys (fentanyl)	Fentanyl sublingual spray; semi-synthetic opioid agonist, approved in 2012.

According to public records compiled by ProPublica, in 2015 alone Medicare Part D paid more than $22 million for claims arising from California physicians' Subsys prescriptions.

[180] *McCaskill: Teva is Stonewalling a Senate Investigation*, HSGAC (Mar. 6, 2018), available at https://www.hsgac.senate.gov/media/minority-media/mccaskill-teva-is-stonewalling-a-senate-investigation (Last Accessed June 7, 2018).

387. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain." The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer." The indication also specifies that "SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.

388. Insys' revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of $331 million. Of that total, $329.5 million was derived from sales of Subsys. The majority of Insys' sales of Subsys are through wholesalers, including defendants AmerisourceBergen, McKesson and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17% and 14% of Insys' total gross sales of Subsys.

389. According to Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing and chief medical officer of the Phoenix House Foundation, fentanyl products are "the most potent and dangerous opioids on the market."[181]

390. The dangers associated with Subsys are reflected by its extremely limited and specific indication, as it is approved solely for BTP in cancer patients already receiving opioids for persistent cancer-related pain.

391. Despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain,

[181] Dina Gusovsky, *The pain killer: A drug company putting profits above patients*, CNBC (Nov. 4, 2015), available at https://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html (Last Accessed June 7, 2018).

neck pain and other off-label pain conditions.[182] Moreover, as of June 2012, Insys defined BTP in cancer patients to include mild pain: a "flare of *mild-to-severe pain* in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Portenoy.[183] Portenoy's paper, "Breakthrough pain: definition, prevalence and characteristics," which was featured in the 1990 issue of Pain, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity (that is, to an intensity of 'severe' or 'excruciating') . . . on a baseline pain of moderate intensity or less." Insys trained and instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

392. According to a 2014 article in *The New York Times,* only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others written by other specialists including dentists and podiatrists.[184]

a. The Indictment of Insys Executives and Arrest of Its Founder

393. On December 8, 2016, several former Insys executives were arrested and indicted for conspiring to bribe practitioners in numerous states, many of whom operated pain clinics, in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, most of whom were not diagnosed with cancer.[185] The indictment alleged that the former executives conspired to mislead and defraud health insurance providers, who were reluctant to approve payment for Subsys when it was prescribed for patients without cancer. In response, the former executives established a "reimbursement unit" at Insys, which was dedicated to assisting physicians by obtaining prior authorization for prescribing Subsys directly from insurers and pharmacy benefit managers.

[182] In the Matter of Insys Therapeutics, Inc., *Notice of Unlawful Trade Practices and Proposed Resolution* (July 10, 2015).
[183] *See* Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 41(3) PAIN 273-81 (July 1990).
[184] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. TIMES (May 13, 2014), available at https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html (Last Accessed June 7, 2018).
[185] *Pharmaceutical Executives Charged in Racketeering Scheme*, DOJ (Dec. 8, 2016), available at https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme (Last Accessed June 7, 2018); United States v. Babich, et al., No. 1 :16-cr-10343-ADB, ECF No. 1 (D. Mass. Dec. 6, 2016), available at https://www.justice.gov/usao-ma/press-release/file/916681/download (Last Accessed June 7, 2018).

Insys reimbursement unit employees were told to inform agents of insurers and pharmacy benefit managers that they were calling "from" or that they were "with" the doctor's office, or that they were calling "on behalf of the doctor."

394. The executive defendants in the indictment include John Kapoor ("Kapoor"), Insys's former CEO and president, as well as the company's former vice president of sales, former national director of sales, former vice president of managed markets and several former regional sales directors. On October 26, 2017, Kapoor— the billionaire founder, CEO and chairman of Insys, who owns a 60% stake in the company — was also charged with fraud and racketeering and was accused of offering bribes to doctors to write large numbers of prescriptions for Subsys. Most of the patients who received the medication did not have cancer.[186]

395. The charges against all seven executives include alleged violations of the federal Anti-Kickback Law, the federal Racketeer Influenced and Corrupt Organizations ("RICO") statute and conspiracy to commit wire and mail fraud, as well as allegations of bribery and defrauding insurers. If found guilty, the defendants face possible sentences of up to 20 years for conspiracy to commit RICO and conspiracy to commit mail and wire fraud, as well as a fine of $250,000 or twice the amount of the pecuniary gain or loss. For the charge of conspiracy to violate the Anti-Kickback Law, the defendants face a sentence of up to five years in prison and a $25,000 fine.

396. The indictment details a coordinated, centralized scheme by Insys to illegally drive profits. The company defrauded insurers from a call center at corporate headquarters where Insys employees, acting at the direction of Insys' former CEO and vice president of managed markets, disguised their identity and the location of their employer and lied about patient diagnoses, the type of pain being treated and the patient's course of treatment with other medication.

397. Harold H. Shaw, special agent in charge of the FBI Boston field division, said in a statement, "[a]s alleged, these executives created a corporate culture at Insys that utilized deception and bribery as an acceptable business practice, deceiving patients, and conspiring with doctors and insurers."

[186] Michela Tindera, *Opioid Billionaire Arrested On Racketeering Charges*, FORBES (Oct. 26, 2017), available at https://www.forbes.com/sites/michelatindera/2017/10/26/opioid-billionaire-arrested-on-racketeering-charges/#707e7d86a005 (Last Accessed June 7, 2018).

398. As set forth in the above-referenced indictment, Insys targeted and bribed practitioners in a number of ways. Insys bribed Subsys prescribers through strategic hires, employing sales representatives and other employees at practitioners' behest and with the expectation that such hires would provide inroads with key practitioners. Further, the indictment alleges that Insys bribed practitioners through a sham speakers' bureau that was purportedly intended to increase brand awareness using peer-to-peer educational lunches and dinners.

399. Specifically, in June 2012, former executives began using in-person meetings, telephone calls and texts to inform Insys sales representatives that the key to sales was using the speakers' bureau to pay practitioners to prescribe Subsys. As one of the company's vice presidents for sales texted one of his sales representatives about potential physicians for the speakers' bureau: "[t]hey do not need to be good speakers, they need to write a lot of [Subsys prescriptions]." The former Insys executives actively recruited physicians known to have questionable prescribing habits for these speakers' bureaus.

400. Speakers' bureaus were often just social gatherings at high-priced restaurants involving neither education nor presentations. Frequently, they involved repeat attendees, including physicians not licensed to prescribe Subsys. Many of the speakers' bureaus had no attendees; sales representatives were instructed to falsely list names of attendees and their signatures on Insys' sign-in sheets.

401. Moreover, the executives are charged with targeting practitioners who prescribed Subsys not only for cancer pain, but for all pain. As set forth in the indictment, at one national speakers' bureau in or about 2014, Insys's then-vice president of sales stated:

> "These [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patients that can go on this drug."

402. The indictment also alleges that, when agents of insurers or pharmacy benefit managers asked if a patient was being treated for BTP in cancer patients, Insys' reimbursement unit employees were instructed to answer using a written script, sometimes called "the spiel": "The physician is aware that the medication is intended for the management of breakthrough pain in cancer

patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable)."

403. Insys's former executives also tracked and internally circulated the number of planned and completed speakers' bureau events for each speaker, as well as the number of Subsys prescriptions each speaker wrote, the percentage of such prescriptions compared to those written for Subsys' competitor drugs, the total amount of honoraria paid to each speaker and, for a period of time, an explicit calculation of the ratio of return on investment for each speaker. When a speaker did not write an appropriate number of Subsys prescriptions, as determined by Insys, the number of future events for which that speaker would be paid would be reduced unless and until he or she wrote more Subsys prescriptions.

404. In a press release issued when the indictment was announced, the Massachusetts U.S. Attorney, Carmen M. Ortiz, stated: "I hope that today's charges send a clear message that we will continue to attack the opioid epidemic from all angles, whether it is corporate greed or street level dealing."

405. In the same press release, the FBI Special Agent in charge of the Boston Field Division, Harold H. Shaw, linked the allegations to the national opioid epidemic:

> ***"As alleged, top executives of Insys Therapeutics, Inc. paid kickbacks and committed fraud to sell a highly potent and addictive opioid that can lead to abuse and life threatening respiratory depression . . . . In doing so, they contributed to the growing opioid epidemic and placed profit before patient safety. These indictments reflect the steadfast commitment of the FBI and our law enforcement partners to confront the opioid epidemic impacting our communities, while bringing to justice those who seek to profit from fraud or other criminal acts."***[187]

406. The Special Agent in Charge at the Defense Criminal Investigative Service in the Northeast Field Office, Craig Rupert, commented specifically on the effect the criminal activities had on members of the military: "Causing the unnecessary use of opioids by current and retired U.S. military service members shows disregard for their health and disrespect for their service to our country…."[188]

[187] https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme (Last visited December 19, 2018).

[188] https://www.fda.gov/iceci/criminalinvestigations/ucm533555.htm (Last visited December 19, 2018).

407. On August 31, 2017, Arizona Attorney General Mark Brnovich filed a lawsuit alleging violations of the ACFA by Insys, two of its former employees and three doctors.[247] Attorney General Brnovich alleged that Insys and its two named employees — former Vice President of Sales Alec Burlakoff and former Manager of Reimbursement Services Elizabeth Gurrieri — engaged in numerous deceptive or unfair acts and practices, including those related to:

- the use of the Insys Reimbursement Center ("IRC"), which was designed to obtain prior authorization for Subsys from insurers and pharmacy benefit managers, misleading consumers about the prior authorization process and the IRC's practices;
- failing to warn consumers about IRC practices, even though Insys knew or had reason to know that healthcare professionals using the IRC would not be in a position to reduce foreseeable risks of harm due to the IRC's practices;
- providing healthcare professionals with false and misleading information, and concealing, suppressing or omitting material facts about the definition of "breakthrough cancer pain" and the FDA-approved uses of Subsys, in order to deceive healthcare professionals so that they would prescribe more Subsys;
- failing to warn consumers of the foreseeable risks of harm from Subsys and Insys' practices while knowing or having reason to know that healthcare professionals to whom Insys provided false and misleading information would not be in a position to reduce the foreseeable risks of harm; and
- providing sham "speaker fees" to healthcare practitioners to induce, and in exchange for, the healthcare practitioners writing Subsys prescriptions.

408. According to the complaint, between March 2012 and April 2017, the three defendant doctors wrote more than $33 million worth of Subsys prescriptions while being paid, on average, approximately $200,000 each in "speaker fees" by Insys.

409. According to the complaint, in order to be booked as speakers and receive speaker fees, doctors were required to have at least 20 patients on Subsys. On the other hand, frequent prescribers of

Subsys were "rewarded" by being paid in speakers fees, which served to "notice[]" "their support of Subsys" with "positive reinforcement."

b. Insys Failed to Report Suspicious Sales as Required

410. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

411. Insys is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

412. The California Code of Regulations requires all drug manufacturers and wholesalers to report "all sales of dangerous drugs subject to abuse" to the Board up to 12 times per year, pursuant to the Board's request. 16 C.C.R. §1782.

413. Insys failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Insys' failure to timely report these and other suspicious sales violated the CSA and California law.

6. Mallinckrodt

414. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs in San Mateo County and nationwide. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

415. Among the drugs it distributes are the following, each of which is a Schedule II drug:

Exalgo (hydromorphone hydrochloride extended release	Opioid agonist indicated for opioid-tolerant patients for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options (*e.g.,* non-opioid analgesics) are inadequate. The FD approved the 8, 12, and 16 mg tablets of Exalgo in March 2012 and 32 mg tablets in August 2012,

Roxicodone (oxycodone hydrochloride)	Brand-name instant-release form of oxycodone hydrochloride. Indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Acquired from Xanodtne Pharmaceuticals in 2012. Strengths range up to 30 mg per pill. Nicknames include Roxies, blues, and stars.
Xartemis XR (oxycodone hydrochloride and acetaminophen	The FDA approved Xartemis XR in March 2014 for the management of acute pain severe enough to require opioid treatment in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. It was the first extended-release oral combination of oxycodone and acetaminophen.
Methadose (methadone hydrochloride)	Branded generic product. Opioid agonist indicated for treatment of opioid addiction.
Morphine sulfate extended release	Generic Product.
Fentanyl extended release	Generic Product.
Fentanyl citrate	Generic Product.
Oxycodone and acetaminophen	Generic Product.
Hydrocodone bitartrate and acetaminophen	Generic Product.
Hydromorphone hydrochloride	Generic Product.
Hydromorphone hydrochloride extended release	Generic Product.
Naltrexone hydrochloride	Generic Product.
Oxymorphone hydrochloride	Generic Product.
Methadone hydrochloride	Generic Product.
Oxycodone hydrochloride	Generic Product.

According to public records compiled by ProPublica, in 2015 alone Medicare Part D paid $1.1 million for claims arising from California physicians' Exalgo, Roxicodone, Xartemis XR and Methadose prescriptions.

7. Actavis

416. Actavis engages in the business of marketing and selling opioids in San Mateo County and throughout the United States, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Kadian is a Schedule II opioid agonist capsule first approved in 1996 and indicated for the "management of pain severe enough to require daily, round-the-clock, long-term opioid treatment and for which alternative treatment

options are inadequate." Prior to 2014, Kadian was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009. (As further background, Pfizer later bought King and Allergan merged with Actavis.)[189]

417. Actavis, like other manufacturers, has spent massive amounts on direct sales contacts with prescribers. In 2014 Actavis spent $2 million dollars.

418. Actavis rolled out a plan in 2008 to move beyond "Kadian loyalists" to an "expanded audience" of "low morphine writers."

419. Actavis knew that one of the largest hurdles to switching patients to its products was out of pocket cost. Actavis decided to lend financial assistance to patients in order to get them using their products. A 2008 Actavis business review, for example, highlighted co-pay assistance, good for up to $600 per patient per year, as a way to drive conversions to Kadian from competitor drugs like Avinza and MS Contin.

420. Ultimately, Actavis, like the other pharmaceutical companies named in this case, overstated the benefits of opioid painkillers while trivializing their risks of addiction, overdose and death, in an effort to boost sales.

VI. CLAIMS

FIRST CLAIM FOR RELIEF

Public Nuisance

Violations of California Civil Code §§3479-3480

(Against All Defendants)

421. Plaintiff incorporates all of the allegations in this complaint.

422. Cal. Civ. Code §3479 provides that "[a]nything which is injurious to health . . . or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property . . . is a nuisance." Cal. Civ. Code §3480 defines

[189] Plaintiff is aware that Allergan and Pfizer are engaged in litigation over which company is responsible for opioid epidemic related costs, and in particular costs related to the improper sales practices surrounding Kadian.

a "public nuisance" as "one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal."

423. Cal. Civ. Proc. Code §731 authorizes the "county counsel of any county in which the nuisance exists" to bring a "civil action . . . to abate a public nuisance." Cal. Civ. Code §3490 states that "[n]o lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right."

424. Each of the Manufacturer Defendants acted in a way that was injurious to the health and interfered with the comfortable enjoyment of life and property of San Mateo County and its residents by, among other things, promoting and marketing the use of prescription opioids for indications not federally approved, circulating false and misleading information concerning prescription opioids' safety and efficacy and/or downplaying or omitting the risk of addiction and overdose arising from the use of prescription opioids. In so doing, each Manufacturer Defendant acted with oppression, fraud or malice.

425. Each of the Defendants unreasonably interfered with the public health, safety, peace and comfort of San Mateo County and its residents by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances or by failing to report suspicious orders of opioids as required by the federal CSA, 21 C.F.R. §1301.74(b), and Cal. Bus. & Prof. Code §§4301 and 4164. In so doing, each defendant acted with oppression, fraud or malice.

426. As detailed herein, Defendants' conduct has interfered with and continues to interfere with rights common to the general public of San Mateo County and has caused it to sustain injury.

427. San Mateo County, acting on its own behalf and on behalf of its residents, seeks costs associated with San Mateo County's efforts to abate the public nuisance caused in whole or in part by Defendants.

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SECOND CLAIM FOR RELIEF

Violation of the California False Advertising Law

(California Business & Professions Code §17500 et seq.)

(Against All Defendants)

428. Plaintiff incorporates herein by reference all of the allegations in this complaint.

429. California Business & Professions Code §17500 et seq. makes it unlawful for a business, with the intent directly or indirectly to dispose of real or personal property, to perform services or to induce the public to enter into any obligation thereto, to make, disseminate or cause to be made or disseminated to the public "any statement, concerning . . . real or personal property . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

430. As alleged above, each Defendant, at all times relevant to this Complaint, violated Section 17500 by making and disseminating false or misleading statements about the use of opioids to treat chronic pain, or by causing false or misleading statements about opioids to be made or disseminated to the public.

431. As alleged above, each Defendant, at all times relevant to this Complaint, violated Section 17500 by making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts, and by failing to correct prior misrepresentations and omissions, about the risks and benefits of opioids. Each Defendant's omissions, which are false and misleading in their own right, render even their seemingly truthful statements about opioids false and misleading.

432. As alleged above, Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by recent pronouncements of the CDC and FDA based on that evidence.

433. As alleged above, each Defendant's conduct, separately and collectively, was likely to deceive California payors who purchased or covered the purchase of opioids for chronic pain.

434. At the time it made or disseminated its false and misleading statements or caused these statements to be made or disseminated, each Defendant knew and should have known that the statements were false or misleading and therefore likely to deceive the public. In addition, Defendants knew and should have known that their false and misleading advertising created a false or misleading impression of the risks and benefits of long-term opioid use and would result in unnecessary and improper opioid prescriptions and use.

THIRD CLAIM FOR RELIEF

UNFAIR COMPETITION

Violations of California Business and Professions Code Section 17200, *et seq.*

(Against all Defendants)

435. Plaintiff re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

436. At a minimum, each Defendant is named in this Cause of Action for its activities that occurred within four years of the filing of this action. Plaintiff reserves the right to prove at trial that the full extent of the Defendants' acts of Unfair Competition was not known to Plaintiff until recently, and Plaintiff also reserves the right to demonstrate that tolling extends the statute of limitations applicable to Plaintiff's claims against Defendants.

437. California Business and Professions Code Section 17200 (Section 17200) prohibits any "unlawful, unfair or fraudulent business act or practice[]."

438. Defendants have engaged in unlawful, unfair, and fraudulent business practices in violation of Section 17200 as set forth above.

439. Defendants' business practices, as described in this Complaint, are deceptive and violate Section 17200 because the practices are likely to deceive consumers in California.

440. Defendants knew or should have known at the time that false and misleading statements about opioids were being made that the statements were in fact false and misleading and were therefore likely to mislead the public. Defendants made or disseminated false and misleading statements or caused false and misleading statements to be made or disseminated, that were likely to deceive the public. Defendants' omissions, which are deceptive and misleading in their own

right, render even Defendants' seemingly truthful statements about opioids false and misleading. All of this conduct, separately and collectively, was likely to deceive California doctors who prescribed opioid medications, patients, and payers, who purchased, or covered the purchase of, opioids for chronic pain, and Counties, such as San Mateo County who were burdened with the aftermath of the opioid epidemic.

441. Defendants' business practices as describe in this Complaint are unlawful and violate Section 17200. These unlawful practices include, but are not limited to:

a. Defendants violated the CSA's requirements as incorporated into California law. Cal. Bus. & Prof. Code §4301;

b. Defendants engaged in acts of gross immorality and aided and abetted the acts of gross immorality by unnamed co-conspirators, including physicians, in violation of Cal. Bus. & Prof. Code §4301;

c. Defendants engaged in acts of incompetence and aided and abetted the acts of incompetence by unnamed co-conspirators, in violation of Cal. Bus. & Prof. Code §4301;

d. Defendants engaged in acts of gross negligence and aided and abetted the acts of gross negligence by unnamed co-conspirators, in violation of Cal. Bus. & Prof. Code §4301;

e. Defendants excessively furnished controlled substances within the County of San Mateo in violation of Cal. Bus. & Prof. Code §4301;

f. Defendants engaged in acts involving moral turpitude, dishonesty, fraud, deceit, and/or corruption and aided and abetted such acts by unnamed co-conspirators, in violation of Cal. Bus. & Prof. Code §4301;

g. Defendants knowingly sold, furnished, gave away, offered to sell, offered to furnish and/or offered to give away controlled opioid substances to addicts in violation of Cal. Bus. & Prof. Code §4301;

h. Defendants violated the statutes of this state, other states and of the United States regulating controlled substances and dangerous drugs in violation of Cal. Bus. & Prof. Code §4301;

i. Defendants violated Cal. Bus. & Prof. Code §4301 by aiding and abetting violations of law by known and unknown co-conspirators, including distributors and physicians which is illegal pursuant to Cal. Bus. & Prof. Code §4301(o);

j. Defendants violated Cal. Health & Safety Code §11153.5 by furnishing for sale and/or distributing opioids that were not solely for legitimate purposes;

k. Defendants failed to report to the California State Board of Pharmacy "all sales of dangerous drugs subject to abuse" in excess of the amounts sets by the Board as required by 16 C.C.R. §1782.

l. Defendants failed to report to the California State Board of Pharmacy suspicious orders placed by one or more California-licensed pharmacy or wholesaler as required by Cal. Bus. & Prof. Code §4169.1.

m. Defendants sold, delivered, held and/or offered for sale opioid drugs that were falsely advertised in violation of the California Sherman Food, Drug, and Cosmetic Laws, Health and Safety Code § 110390;

n. Defendants, sold, delivered, held, or offered for sale opioids that had been falsely advertised in violation of the California Sherman Food, Drug, and Cosmetic Laws, Health & Safety Code § 110395;

o. Defendants received in commerce opioids that were falsely advertised or delivered or proffered for delivery opioids that were falsely advertised in violation of the California Sherman Food, Drug, and Cosmetic Laws, Health & Safety Code § 110400;

p. Defendants sold, delivered, held, or offered for sale opioids that had been misbranded in violation of the California Sherman Food, Drug, and Cosmetic Laws, Health & Safety Code §§ 110290, 111440, and 111330;

q. Defendants misbranded opioids in violation of the California Sherman Food, Drug, and Cosmetic Laws, Health & Safety Code §§ 110290, 111445, 111330;

r. Defendants received in commerce opioids that were misbranded in violation of the California Sherman Food, Drug, and Cosmetic Laws, Health & Safety Code §§ 110290, 111450, and 111330;

s. Defendants proffered for delivery opioids that were misbranded in violation of the California Sherman Food, Drug, and Cosmetic Laws, Health & Safety Code §§ 110290, 111450, and 111330;

t. Defendants failed to adopt and comply with a Comprehensive Compliance Program in violation of Health & Safety Code § 119402;

u. Defendants represented that opioids had sponsorship, approval, characteristics, ingredients, uses, or benefits which they did not have in violation of the Consumer Legal Remedies Act, Civ. Code § 1770(a)(5);

v. Defendants represented that opioids were of a particular standard, quality, or grade when they were of another in violation of California Consumer Legal Remedies Act, Civ. Code § 1770(a)(7);

w. Defendants disparaged the goods of another by false or misleading representation of fact in violation of California Consumer Legal Remedies Act, Civ. Code § 1770(a)(8);

x. Defendants unlawfully failed to identify and report suspicious prescribing to law enforcement and health authorities;

y. Defendants made or disseminated, directly or indirectly, untrue, false, or misleading statements about the use of opioids to treat chronic pain, or caused untrue, false, or misleading statements about opioids to be made or disseminated to the general public in violation of California Bus. & Prof. Code Section 17500; and,

z. Defendant Purdue directly or indirectly offered or paid remuneration to doctors to prescribe its opioids in violation of California Welfare and Institutions Code § 14107.2.

442. Defendants' business practices as described in this Complaint are unfair and violate California Bus, & Prof. Code Section 17200 because they offend established public policy, and because the harm they cause to consumers in California greatly outweighs any benefits associated with those practices.

443. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits associated with those practices, which they would not have received if they had not engaged in violations of the UCL described in this Complaint.

444. As a direct and proximate result of the foregoing acts and practices, Defendants have obtained an unfair advantage over similar businesses that have not engaged in such practices.

FOURTH CLAIM FOR RELIEF

Negligence

(Against All Defendants)

445. Plaintiff incorporates herein by reference all of the allegations in this complaint.

446. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty and the plaintiff sustains harm proximately caused by the defendant's breach. A presumption of negligence (negligence per se) is established where a defendant's negligence involves the violation of a statute or regulation, where plaintiff is within the class of persons that the

statute or regulation was designed to protect and the violation is a substantial factor in the plaintiff's harm.

447. Each of the Manufacturer Defendants owed Plaintiff duties under statutory and common law, including: (1) the duty to comply with Cal. Bus. & Prof. Code §17200 *et seq*.'s prohibition on unlawful, unfair or fraudulent business acts or practices, Cal. Bus. & Prof. Code §17500 *et seq*.'s prohibition on the dissemination of untrue and misleading statements, and the Consumers Legal Remedies Act ("CLRA"); (2) the duty to promote and market prescription opioids truthfully and without misleading statements and omissions; and (3) the duty to disclose the true risk of addiction associated with the use of prescription opioids.

448. Each of the Manufacturer Defendants breached these duties by, among other things, promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information to prescribers, regulators and the public concerning their products and downplaying or omitting the risk of addiction arising from their use.

449. Each of the Defendants owed Plaintiff duties under statutory and common law, including: (1) the duty not to fill suspicious or excessive orders; (2) the duty to abide by any government agreements entered into regarding the same; and (3) the duty to comply with the federal CSA, 21 C.F.R. §1301.74(b), 16 C.C.R. §1782 as set forth above, and Cal. Bus. & Prof. Code. §§4301 and 4164, which required the design and operation of a system to detect and disclose suspicious orders of controlled substances.

450. Each of the Defendants breached these duties by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report such suspicious orders to the appropriate regulators as required by state and federal law.

451. Each of the Manufacturer Defendants owed Plaintiff additional duties under statutory law including: (1) the duty under Cal. Health & Safety Code §11153.5 to ensure that all of the opioids they distributed and furnished for sale in California and its counties were furnished only for legitimate medical purposes; and (2) the duty under Cal. Bus. & Prof. Code §4169.1, which requires them to report suspicious orders of opioids.

452. Each Manufacturer Defendant breached these duties by failing to take any reasonable measures to ensure that the prescription opioids it distributed and furnished for sale in San Mateo County were furnished only for legitimate medical purposes and by failing to track and report suspicious sales.

453. Plaintiff was within the protected class of persons that the UCL, the CLRA, Cal. Bus. & Prof. Code §§4301, 4164 and 17500, 21 C.F.R. §1301.74(b), Cal. Health & Safety Code §11153.5 and 16 C.C.R. §1782 were designed to protect.

454. Plaintiff has suffered damages directly, proximately and foreseeably caused by Defendants' breaches of their statutory and common law duties.

455. Defendants' negligent acts as set forth herein were made with oppression, fraud or malice.

FIFTH CLAIM FOR RELIEF

Negligent Misrepresentation

(Against the Manufacturer Defendants)

456. Plaintiff incorporates herein by reference all of the allegations in this complaint.

457. A defendant is liable for negligent misrepresentation where it, in the course of its business, profession or employment, or in any other transaction in which it has a pecuniary interest, supplies false information for the guidance of others in their business transactions and the defendant fails to exercise reasonable care or competence in obtaining or communicating the false information at issue.

458. The Manufacturer Defendants are liable for the pecuniary loss caused to San Mateo County by its justifiable reliance upon the information. In the course of their businesses, each Manufacturer Defendant made and caused to be made affirmatively false statements about prescription opioids, including, but not limited to, statements and omissions concerning the safety and efficacy of prescription opioids and the risk of addiction and overdose associated therewith. Each Manufacturer Defendant failed to exercise reasonable care and competence in communicating the false information.

459. Each Manufacturer Defendant wrongfully concealed the falsity of its statements, the truth about which Plaintiff did not discover until recently, despite exercising due diligence. Plaintiff, Plaintiff's agents, persons on whom Plaintiff and its agents justifiably relied, Plaintiff's communities and the public justifiably relied on the false information the Manufacturer Defendants provided, just as the Manufacturer Defendants had intended.

460. Each Manufacturer Defendant's dissemination of false statements demonstrated a conscious disregard for the rights and safety of other persons that had a great probability of causing substantial harm.

461. As a direct and proximate result of the Manufacturer Defendants' affirmatively false statements, Plaintiff suffered damages.

SIXTH CLAIM FOR RELIEF

Fraudulent Concealment

(Against the Manufacturer Defendants)

462. Plaintiff incorporates herein by reference all of the allegations in this complaint.

463. At all times relevant, each Manufacturer Defendant concealed and intentionally failed to disclose material facts known to it including that: (1) there was no basis for making claims as to prescription opioids' safety or efficacy for the treatment of certain indications for which each Manufacturer Defendant promoted them; and (2) there was no basis for its representations concerning the risk of addiction and overdose resulting from the use of prescription opioids, which each Manufacturer Defendant substantially understated.

464. Each Manufacturer Defendant intended the omission of the concealed facts to deceive Plaintiff:

465. Plaintiff was unaware of the concealed facts. Had Plaintiff known the truth about the concealed facts, Plaintiff would not have authorized and paid for certain prescription opioid treatments for its residents.

466. Each Manufacturer Defendant's failure to disclose information about the true level of addictiveness of prescription opioids deceived Plaintiff and was a substantial factor in causing Plaintiff to pay for prescription opioids for uses that were not medically necessary.

467. Plaintiff was damaged due to its justified reliance on each of the Manufacturer Defendant's concealments, which were made with oppression, fraud or malice.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that this Court grant the following relief:

468. Entering Judgment in favor of the County of San Mateo in a final order against each of the Defendants;

469. A declaration that Defendants have created a public nuisance in violation of Civil Code Sections 3479 and 3480;

470. An order that Defendants are required to abate the public nuisance that they created in violation of Civil Code Sections 3479 and 3480;

471. An order that Defendants fund an "abatement fund" on behalf of San Mateo County for the purposes of prospectively abating the ongoing opioid nuisance;

472. An order that Defendants compensate San Mateo County for damages to its property due to the ongoing public nuisance caused by the opioid epidemic;

473. A declaration that Defendants have engaged in unlawful, unfair, and deceptive business acts and practices in violation of the Unfair Competition Law;

474. A declaration that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;

475. An order that Defendants pay restitution to San Mateo County of any money acquired by Defendants' false and misleading advertising, pursuant to the False Advertising Law and Unfair Competition Law;

476. An award of damages to San Mateo County for the damages caused by the opioid epidemic, including (A) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction, dependence or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for providing care for

children whose parents suffer from opioid-related disability or incapacitation; and (E) costs associated with law enforcement and public safety relating to the opioid epidemic;

477. An award of punitive damages;

478. An award of the costs of investigation, reasonable attorneys' fees, and all costs and expenses of the litigation;

479. Such further and additional relief as the Court deems proper.

VIII. JURY DEMAND

Plaintiff demands a jury trial on all issues so triable.

Dated: February 21, 2019

COUNTY OF SAN MATEO, COUNTY COUNSEL

By: */s/ John C. Beiers*
JOHN C. BEIERS
JOHN D. NIBBELIN
DAVID SILBERMAN
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Dated: February 21, 2019

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