IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, CHANCERY DIVISION

CITY OF HARVEY, VILLAGE OF BROADVIEW, VILLAGE OF CHICAGO RIDGE, VILLAGE OF DOLTON, VILLAGE OF HOFFMAN ESTATES, VILLAGE OF MAYWOOD, VILLAGE OF MERRIONETTE PARK, VILLAGE OF NORTH RIVERSIDE, VILLAGE OF ORLAND PARK, CITY OF PEORIA, VILLAGE OF POSEN, VILLAGE OF RIVER GROVE, VILLAGE OF STONE PARK, and ORLAND FIRE PROTECTION DISTRICT,

Plaintiffs,

v.

PURDUE PHARMA L.P., PURDUE PHARMA, INC., PURDUE FREDERICK COMPANY, INC., RHODES PHARMACEUTICALS, CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., ENDO INTERNATIONAL PLC, JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, INC., ORTHO-MCNEIL-JANSSEN PHARMACUETICALS, INC., JANSSEN PHARMAEUTICA, INC., INSYS THERAPEUTICS, INC., NORMACO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., ALLERGAN PLC, ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS PHARMA, INC., ACTAVIS LLC, MALLINCKRODT PLC, MALLINCKRODT LLC, AMERISOURCEBERGEN CORPORATION, CARDINAL HEALTH, INC., MCKESSON CORPORATION, PAUL MADISON, WILLIAM MCMAHON, and JOSEPH GIACCHINO,

Defendants.

Case No. 2018CH09020

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs City of Harvey, Village of Broadview, Village of Chicago Ridge, Village of Dolton, Village of Hoffman Estates, Village of Maywood, Village of Merrionette Park, Village

of North Riverside, Village of Orland Park, City of Peoria, Village of Posen, Village of River Grove, Village of Stone Park, and Orland Fire Protection District bring this Complaint and Demand for Jury Trial to obtain redress in the form of monetary and injunctive relief from Defendants for their role in the opioid epidemic that has caused widespread harm and injuries to Plaintiffs' communities. Plaintiffs, for their Complaint, allege as follows:

NATURE OF THE ACTION

1. Prescription opioids are devastating communities across the country and in the State of Illinois. Since 1999, there have been more than 351,000 reported opioid-related deaths nationwide—more than 6 times the number of U.S. soldiers who died in the Vietnam War. Today, an American dies from an opioid overdose every 19 minutes and more than 60% of all drug overdose deaths in the United States involve an opioid.

2. In addition to the tragic loss of life and the heartbreaking impact on children and loved ones, some estimates state that the opioid crisis is costing governmental entities and private companies as much as $500 billion per year.

3. This epidemic and its consequences could and should have been avoided. However, Defendants—opioid manufacturers, wholesale distributors, and local prescribers—intentionally and negligently created conditions that allowed vast quantities of opioids flow freely to patients Plaintiffs' communities who should have never obtained them. Instead of truthfully and safely marketing their products, Defendants blindly stoked the engine of opioid prescribing to obtain untold profits from their sales.

4. The crux of Defendants' deceptive conduct involved a years' long campaign to misrepresent the risks of, and shift public opinion on, the use of prescription opioids to treat chronic non-cancer pain. Defendant manufacturers purposefully and aggressively marketed

opioid products for unapproved uses, buried unfavorable research, and employed a network of phony front groups, opinion leaders, and sales representatives to expand the market for opioids and obtain massive profits.

5. Further down the supply chain, distributors are supposed to serve as a check on the diversion and misuse of prescription opioids, in part by implementing appropriate monitoring systems to identify "red flags" in opioid ordering. But Defendant distributors utterly failed in this duty, failing to implement basic controls to prevent opioid diversion that subsequently (and predictably) became widespread in Plaintiffs' communities. Instead of serving as gatekeepers, Defendant opioid distributors pursued blockbuster profits by throwing open the gates and looking the other way, as millions upon millions of doses of prescription opioids flooded into cities, towns, and villages throughout Illinois.

6. At the end of the opioid supply chain, Defendants Paul Madison, William McMahon, and Joseph Giacchino were working around the clock to prescribe opioids to anyone who came through the door of their clinic in Riverside, Illinois—whether or not they had a valid need for them, were from out-of-state, or presented any number of patently suspicious traits. The pill mill they operated distributed thousands upon thousands of opioid prescriptions to countless residents of Plaintiffs' communities, completing a chain of indifferent profiteering that has marked the acts—and omissions—of all Defendants' conduct in making, distributing, and selling prescription opioids.

7. Defendants' indifference has taken a dramatic toll on Plaintiffs' communities. Drug abuse, addiction, overdose, and crime caused by Defendant's illicit activities have imposed, and will continue to impose, tremendous social and economic costs on Plaintiffs. Plaintiffs have spent significant taxpayer money to combat opioid abuse and addiction, including substantial

excess expenditures on law enforcement, criminal justice services, and emergency medical services, as well as significant costs to its employee health insurance program due to paying for opioids that should have never been prescribed.

8. These injuries were a direct and foreseeable consequence of Defendants' grossly deceptive practices and unwillingness to regulate the distribution of prescription opioids. Because Defendants injured Plaintiffs and their residents through these acts and omissions, they are liable to them for creating a public nuisance, negligence, fraudulent misrepresentation, insurance fraud, consumer fraud, and unjust enrichment.

JURISDICTION AND VENUE

9. Pursuant to the Illinois Constitution art. VI § 9, this Court has subject matter jurisdiction over Plaintiffs' claims.

10. This Court has jurisdiction over each Defendant pursuant to 735 ILCS 5/2-209 because they have conducted business transactions in Illinois, committed tortious acts in Illinois, and transacted substantial business in Illinois which has caused harm in Illinois.

11. Venue is proper in Cook County because Defendants have conducted business transactions in Cook County and the causes of action arose, in substantial part, in Cook County.

PARTIES

12. As used throughout this Complaint unless otherwise provided, the phrase "relevant time period" is defined as beginning on January 1, 1997, and ending on the date of the filing of this Complaint.

Plaintiffs

13. Plaintiff City of Harvey is a municipal corporation existing under the laws of the State of Illinois and located in the County of Cook.

14. Plaintiff Village of Broadview is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

15. Plaintiff Village of Chicago Ridge is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

16. Plaintiff Village of Dolton is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

17. Plaintiff Village of Hoffman Estates is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

18. Plaintiff Village of Maywood is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

19. Plaintiff Village of Merrionette Park is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

20. Plaintiff Village of North Riverside is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

21. Plaintiff Village of Orland Park is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

22. Plaintiff City of Peoria is a municipal corporation existing under the laws of the State of Illinois and located in Peoria County.

23. Plaintiff Village of Posen is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

24. Plaintiff Village of River Grove is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

25. Plaintiff Village of Stone Park is a municipal corporation existing under the laws

of the State of Illinois and located in Cook County.

26. Plaintiff Orland Fire Protection District is a municipal corporation existing under the laws of the State of Illinois and located in Cook County.

Manufacturer Defendants

27. Defendant Purdue Pharma L.P. ("Purdue L.P.") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma, Inc. ("Purdue Inc.") is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. ("Purdue Frederick") is a New York corporation with its principal place of business in Stamford, Connecticut. Rhodes Pharmaceuticals, L.P. ("Rhodes") is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. These four entities are collectively referred to herein as "Purdue" unless otherwise specified.

28. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business is Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation and wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva Ltd. and Teva USA acquired Cephalon in 2011. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. These three entities—Teva Ltd., Teva USA, and Cephalon—are referred to as "Cephalon" herein, unless otherwise specified.

29. Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson, Inc. ("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 over 10 percent of Janssen's stock, the company and corresponds with the FDA regarding Janssen's products. Upon information and belief, Johnson & Johnson controls the sale and development of Janssen's drugs, and Janssen's profits inure to Johnson & Johnson's benefit. Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware, and was a wholly owned subsidiary of Johnson & Johnson until July 2016. Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho-McNeil-Janssen") and Janssen Pharmaceutica, Inc., ("Jansen Pharmaceutica") are both Pennsylvania corporations with their principal places of business in Titusville, New Jersey. Both are now known as Janssen Pharmaceuticals, Inc. These entities—Janssen, Johnson & Johnson, Normaco, Ortho-McNeil-Janssen, and Janssen Pharmaceutica—are referred to herein as "Janssen" unless otherwise specified.

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

31. Endo Health Solutions, Inc. ("Endo Health Solutions") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. ("Endo Pharmaceuticals") is a wholly owned subsidiary of Endo Health Solutions, and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. These entities are referred to as "Endo" herein, unless otherwise specified.

32. Allergan PLC ("Allergan") is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC ("Actavis") acquired Allergan in March 2015. Before that, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") acquired Actavis in October 2012. Watson Laboratories, Inc. ("Watson Labs") is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned

subsidiary of Allergan. Actavis Pharma, Inc. ("Actavis Pharma") 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.

33. Allergan owns each of these Defendants and uses them to market and sell its drugs in the United States. Upon information and belief, Allergan exercises control over these marketing and sales efforts, and profits from the sale of Allergan and Actavis products ultimately inure to its benefit. As such, Allergan, Actavis, Watson Pharmaceuticals, Watson Labs, Actavis Pharma, and Actavis LLC are referred to herein as "Actavis" unless otherwise specified.

34. Mallinckrodt, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with a U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC. These entities are referred to herein as "Mallinckrodt" unless otherwise specified.

35. Collectively, Purdue, Cephalon, Endo, Janssen, Insys, Actavis and Mallinckrodt are referred to as "Manufacturer Defendants" herein when describing the activities of these parties together, and as "Defendants" when describing them along with the other Defendants in this action.

Distributor Defendants

36. AmerisourceBergen Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania. AmerisourceBergen operates a distribution center in Romeoville, Illinois.

37. Cardinal Health, Inc. ("Cardinal Health") is an Ohio corporation with its principal

office location in Dublin, Ohio. Cardinal Health operates distribution centers in Aurora and Waukegan, Illinois.

38. McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California. McKesson operates a distribution centers in Aurora, Illinois.

39. Collectively, AmerisourceBergen, Cardinal Health, and McKesson collect about 85 percent of the revenues for prescription drugs distribution in the United States.

40. AmerisourceBergen, Cardinal Health, and McKesson are referred to herein as "Distributor Defendants" when describing the activities of the three parties together, and as "Defendants" when describing them along with the other Defendants in this action.

Prescriber Defendants

41. Defendants Paul Madison, William McMahon, and Joseph Giacchino (collectively, "Prescriber Defendants") are natural persons and residents of Illinois. Prescriber Defendants operated and worked at the now-defunct medical clinic, Melrose Park Clinic, Ltd., a/k/a Riverside Pain Management, at 28 East Burlington Street, Riverside, Illinois, from January 2013 until March 10, 2017. With Giacchino's administrative and managerial assistance, McMahon and Madison wrote opioid prescriptions for the clinic's patients during the entire time of its operation.

42. Prior to this, Giacchino operated and wrote opioid prescriptions at the Melrose Park Clinic at 1252 Winston Plaza, Melrose Park, Illinois, from June 11, 1985, until the revocation of Giacchino's medical license in 2011.

43. As of today, all three Prescriber Defendants are no longer licensed to practice medicine. Defendant Giacchino's medical license was permanently revoked by the Illinois

Department of Financial and Professional Regulation in 2011, in relation to his over-prescribing of opioids, among other charges. *See Giacchino v. Ill. Dep't of Fin. & Prof'l Regulation, et al.*, 2013 IL App (1st) 122694-U, ¶ 74. Defendant McMahon's medical license was permanently revoked in November 2016 by the Illinois Department of Financial and Professional Regulation, in relation to his over-prescribing of opioids. Defendant Madison's medical license was suspended by the Illinois Department of Financial and Professional Regulation in November 2016, in relation to his over-prescribing of opioids.

FACTUAL ALLEGATIONS

I. Prescription Opioids Are Dangerous Narcotics With No Demonstrated Use For Treating Chronic Non-Cancer Pain, And Are At The Center Of An Epidemic.

44. To explain the nature of Defendants' illegal conduct, it is first necessary to explain how prescription opioids work—and don't—in order to understand how they sparked an ongoing epidemic of addiction in Plaintiffs' communities and nationwide.

A. Background on Prescription Opioids.

45. The term opioid means "opium-like," and includes all drugs derived in whole or in part from the opium poppy.

46. In the medical field, opioids are a class of drugs and analgesic (*i.e.*, pain-relieving) agents that include pain relief drugs obtainable by prescription, such as oxycodone, hydrocodone, codeine, morphine, and fentanyl, as well as the illegal drug heroin. Upon ingestion, opioids attach to specific proteins called "opioid receptors," which are distributed throughout the body's central nervous system. When activated, these receptors produce analgesic effects and a sense of euphoria in the user.[1]

[1] *See* Hasan Pathan & John Williams, *Basic Opioid Pharmacology: An Update*, 6 British J. of Pain 11 (2012).

47. Opioid users develop a tolerance for the drug. As a 2002 paper describes, "[r]epeated exposure to escalating dosages of opioids alters the brain so that it functions more or less normally when the drugs are present and abnormally when they are not."[2] As time goes by, the opioid user needs more and more opioids to feel "normal," produce pleasure comparable to prior opioid uses, and to avoid any negative symptoms of withdrawal.[3] However, opioid tolerance may begin to develop after a single dose, particularly with regard to the drug's analgesic and euphoric effects.[4]

48. This vicious cycle, if not checked, results in addiction: "opioids not only directly activate these brain analgesia and reward regions but also concurrently mediate a learned association between receipt of the drug and the physiological and perceptual effects of the drug—a type of Pavlovian conditioning."[5]

49. Thus, opioid use can readily lead to addiction, misuse, dependence, and abuse—and indeed, it has, with the United States' present opioid epidemic being described by some as "the worst drug crisis in American history."[6] For instance, opioid users may also seek to increase their dosage and maintain their euphoric high by snorting or injecting crushed opiate pills and

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[2] Thomas R. Kosten & Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 Sci. & Practice Perspectives 14 (July 2002), *available at* http://bit.ly/2DwcTP1.

[3] Thomas R. Kosten & Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 Sci. & Practice Perspectives 15 (July 2002), *available at* http://bit.ly/2DwcTP1.

[4] Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain – Misconception and Mitigation Strategies, 374 N. Eng. J. Med. 1253 (2016); Jessica Wapner, *CDC Study Finds Opioid Dependency Begins Within a Few Days of Initial Use*, Newsweek (Mar. 22, 2017), http://www.newsweek.com/cdc-opiate-addiction-572498.

[5] Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain – Misconception and Mitigation Strategies, 374 N. Eng. J. Med. 1253 (2016).

[6] Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain – Misconception and Mitigation Strategies, 374 N. Eng. J. Med. 1253 (2016); Dan Nolan, *How Bad is the Opioid Epidemic?*, Frontline (Feb. 23, 2016), https://www.pbs.org/wgbh/frontline/article/how-bad-is-the-opioid-epidemic/.

tampering with extended release tablets.[7] They may also transition to cheaper black market opioids such as heroin—according to the National Institute on Drug Abuse, nearly 80 percent of heroin users report misusing prescription opioids before turning to the cheaper, more-powerful drug.[8] The CDC has also noted that addiction to prescription pain medication is the strongest risk factor leading to heroin addiction, with those addicted to opioid pills being 40 times more likely to become addicted to heroin.[9]

50. In 2015, over two million people in the United States had a substance abuse disorder involving prescription opioids.[10]

51. A narcotic is a potential analgesic drug used to treat several episodes of pain. Narcotic drugs, such as opioids, work on pain receptors in the brain to relieve pain, but do not decrease inflammation.

52. Because of their potent analgesic and euphoric effects, along with its high potential for addiction (particularly when used for extended periods), prescription opioids like oxycodone and hydrocodone have been classified as Schedule II narcotics under the federal Controlled Substances Act. 21 C.F.R. § 1308.12. Schedule II is a category that includes substances like methamphetamine and cocaine.

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[7] Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016);

[8] Nat. Institute on Drug Abuse, *DrugFacts: What is Heroin?* (last revised Jan. 2018), https://www.drugabuse.gov/publications/drugfacts/heroin#ref; *see also* Pradip K. Muhuri, et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Ctr. for Behavior Health Stats. & Quality Data Rev. (Aug. 2013), http://bit.ly/2G7PFfH.

[9] *See* Ctrs. for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015); *see also* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

[10] Am. Soc. Of Addiction Med., *Opioid Addiction Facts and Figures* 1 (last visited Jan. 24, 2018), https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

53. Opioids have a demonstrated, scientifically-proven use in treating "breakthrough" acute cancer-related pain, and have been prescribed for years to treat such pain. "Breakthrough" pain refers to pain that "breaks through" the relief provided by an existing regimen of pain relievers.

54. While opioids have also been prescribed for years to treat breakthrough chronic non-cancer pain, the efficacy of long-term opioid use for such ailments has never been reliably demonstrated through sufficient evidence or high-quality scientific research.[11] There have been few randomized controlled trials regarding opioid efficacy for non-cancer pain and even fewer double-blind studies.

55. Critically, while short-term use of opioids for "break through" pain became part of the medical consensus, no studies have found that long-term opioid is beneficial.[12]

56. As a 2006 Canadian meta-analysis found, a majority of studies of opioid use related to chronic non-cancer pain were funded by the pharmaceutical industry itself, and *none* had found concrete evidence of opioids improving functioning over non-opioid analgesics.

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[11] Hasan Pathan & John Williams, *Basic Opioid Pharmacology: An Update*, 6 British J. of Pain 11, 15 (2012). Opioids' use as a predictable, effective source of short-term pain relief has even been called into question. A 2004 meta-analysis of literature published between 1996 and 2003 on opioids and pain relief found that, in patients taking doses for periods of up to eight weeks, opioid use only reduced reported pain by 2 points on a "1 to 10" pain scale, or a 30 percent reduction of pain compared to patients taking placebos. For some conditions, opioids provided either an insignificant reduction in pain over a placebo or failed to provide at least a 30% reduction in pain. Thus, Dr. Andrea Rubinstein, MD, concludes that even short-term opioid efficacy is a "far cry from the 'complete relief' expected by many patients." *See* Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Mag. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747; *see also* Eija Kalso, et al., *Opioids in Chronic Non-Cancer Pain: Systemic Review of Efficacy and Safety*, 21 PAIN 372 (2004).

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

Instead, the Canadian analysis concluded, "for functional outcomes the other analgesics were significantly more effective than were opioids."[13]

57. A 2006 Danish study had even blunter findings, stating that "it is remarkable that *opioid treatment of chronic non-cancer pain does not seem to fulfill any of the key outcome goals: pain relief, improved quality of life, and improved functional capacity*."[14]

58. The FDA essentially reiterated this point in a 2013 letter, stating that it was unaware "of [any] adequate and well-controlled studies of opioid use longer than 12-weeks."[15]

59. The Centers for Disease Control ("CDC") has come to the same conclusion. In 2016 the CDC published a Guideline for Prescribing Opioids for Chronic Pain following a "systematic review of the best available evidence" by a panel of experts free from conflicts of interest. The CDC found no long-term studies of opioid use effectiveness for chronic pain, function, or patient quality of life.[16]

60. One thing is certain about opioids, however: "prescribing opioids for their analgesic effects will typically require increasingly higher doses in order to maintain the initial level of analgesia—up to 10 times the original dose."[17]

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[13] Andrea D. Furlan, et al., *Opioids for Chronic Noncancer Pain: A Meta-analysis of Effectiveness and Side Effects*, 174 Canadian Med. Ass'n J. 1589 (2006).

[14] Jorgen Eriksen, et al., *Critical Issues on Opioids in Chronic Non-Cancer Pain: An Epidemiological Study*, 125 Pain 172, 176–77 (2006) (emphasis added).

[15] Letter from Janet Woodcock, M.D., Director, Ctr. For Drug Evaluation & Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), *available at* http://bit.ly/2F430US.

[16] Deborah Dowell, et al, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, Ctrs. for Disease Control (Mar. 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[17] Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain – Misconception and Mitigation Strategies, 374 N. Eng. J. Med. 1253 (2016); *see also* Chante Buntin-Mushock, et al., *Age-Dependent Opioid Escalation in Chronic Pain Patients*, 100 Anesthesia & Analgesia 1740 (2005) (noting observation of "[r]apid opioid dose escalation" in daily opioid therapy patients in a study assessing the relationship between age and opioid tolerance).

61. Despite this, "opioids are … frequently prescribed within the [medical] community, where codeine, oxycodone and buprenorphine are commonly used for chronic pain" treatment.[18] How opioids came to be widely prescribed for long-term use—without scientific proof that they even worked for that purpose—is the focus of this lawsuit.

62. The risks of opioid treatment for chronic pain are high, as patients who receive increasing doses of opioids for the treatment of chronic non-cancer pain have as much as a nine times higher chance of overdose.[19] Indeed, studies on opioid use have demonstrated a correlation between high opioid dosage and poor physical function, as well as worsened overall general health.[20] Another study confirmed that patients using opioids for chronic pain scored lower than non-opioid users across multiple criteria such as physical function, social function, vitality, and pain.[21]

63. Opioid use also delays injury recovery and increases the risk of permanent disability. In a study of Workers Compensation claims for lower back pain, increasing a patient's opioid dosage was found to correlate with an increasing risk of disability compared to non-opioid users.[22] Another study showed that prescribing opioids within six weeks of an injury actually

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[18] Hasan Pathan & John Wiliams, *Basic Opioid Pharmacology: An Update*, 6 British J. of Pain 11, 15 (2012).

[19] Kate M. Dunn, et al., Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study, 152 Ann. Intern. Med. 85 (2010).

[20] Kathryn Sullivan Dillie, et al., Quality of Life Associated With Daily Opioid Therapy in a Primary Care Chronic Pain Sample, 21 J. of the Am. Bd. Of Fam. Med. 108 (2008).

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

[22] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat. Safety Council (2016), *available at* http://bit.ly/2DGQtKT (citing Barbara S. Webster, et al., *Relationship Between Early Opioid Prescribing for Acute Occupation Low Back Pain and Disability Duration, Medical Costs, Subsequent Surgery, and Late Opioid Use*, 32 Spine 2127 (Sept. 2007)).

doubled the risks of disability one year later.[23] Likewise, studies on opioid use prior to back surgery show poorer outcomes for patients including increased pain, decreased function, and increased depression.[24]

64. Worst of all, opioid use can ultimately lead to death by overdose—and does, with a frequency that has led the medical profession, the federal government, the media, and even (in some cases) Defendants to describe the current state of affairs as an "epidemic" or "crisis."[25]

B. The National Opioid Epidemic.

65. Today, opioids are the main driver of drug overdose deaths in the United States.[26] From 1999 to 2014, more than 165,000 Americans died from an overdose related to opioid use.[27] In 2015 alone, 35,000 Americans died from opioid-related deaths.[28]

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[23] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat. Safety Council (2016), *available at* http://bit.ly/2DGQtKT (citing Gary M. Franklin, et al., *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: the Disability Risk Identtification Study Cohort*, 33 Spine 199 (2008)).

[24] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat. Safety Council (2016), *available at* http://bit.ly/2DGQtKT (citing Sheyan J. Armaghani, et al., *Preoperative Opioid Use as a Predictor of Adverse Postoperative Self-Reported Outcomes in Patients Undergoing Spine Surgery*, 96 J. Bone & Joint Surgery (American) e89 (2014)).

[25] *See, e.g.*, Proclamation No. 9499, 81 Fed. Reg. 65,172 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Awareness Week."); Ctrs. for Disease Control and Prevention, *Today's Heroin Epidemic* (last updated July 7, 2015), https://www.cdc.gov/vitalsigns/heroin/index.html; Elizabeth Cohen, *US Surgeon General Sends Warning Letter To All Doctors On Opioid Epidemic*, CNN (Aug. 25, 2016), https://www.cnn.com/2016/08/25/health/us-surgeon-general-letter-doctors-opioid-use/index.html; AmerisourceBergen, *Fighting the Opioid Epidemic* (last visited Mar. 1, 2018), https://www.amerisourcebergen.com/abcnew/fighting-the-opioid-epidemic.

[26] See Ctrs. For Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Opioid Overdose, (December 16, 2016), https://www.cdc.gov/drugoverdose/data/statedeaths.html.

[27] Deborah Dowell, et al, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, Ctrs. for Disease Control (Mar. 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[28] *Overdose Death Rates | National Institute on Drug Abuse (NIDA),* https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (last visited January 2, 2018).

66. This rise in overdose deaths has been a major contributor to the decline in U.S. life expectancy, which fell in 2015 and 2016—the first such multi-year drop since the early 1960s.[29]

67. Prescription opioids' increasingly wide usage has been the key feature of these problems. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a five-milligram dose of hydrocodone every four hours for one month.[30]

68. In 2011, the CDC declared prescription painkiller overdoses to be at epidemic levels, noting that over 40 people die per day from overdoses of narcotic pain relievers like Vicodin, OxyContin, and Opana, and that nearly 5,500 people begin misusing prescription painkillers every day.[31]

69. Today, the number of opioid prescriptions issued annually in the United States is roughly equal to the size of its entire adult population.[32] And the explosive growth in painkiller prescriptions has been concurrent with a rise in heroin deaths across the country, with the CDC reporting a tripling of heroin overdoses between 2010 and 2014 alone.[33]

70. The societal costs of prescription opioid abuse are enormous. Across the country, local governments are struggling with a pernicious, ever-expanding epidemic that "affects public health as well as social and economic welfare," according to the National Institute on Drug

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[29] Rob Stein, *Life Expectancy Drops Again As Opioid Deaths Surge in U.S.*, NPR (Dec. 21, 2017), https://www.npr.org/sections/health-shots/2017/12/21/572080314/life-expectancy-drops-again-as-opioid-deaths-surge-in-u-s.

[30] Katherine M. Keyes, et al., *Trends In Opioid Analgesic Abuse And Mortality In The United States*, 372 N. Eng. J. Med. 241 (2015).

[31] *See* Press Release, Ctrs. For Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Prescription Painkiller Overdoses At Epidemic Levels* (Nov. 1, 2011).

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

[33] *See* Rose A. Rudd, et al., *Increases In Drug And Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

Abuse.[34] Estimates of the total financial impact of this burden—including the costs of providing health care, lost worker productivity, and criminal justice-related costs—reach as high as $500 *billion*.[35]

71. As the crisis continues to take a toll on communities around the country, the manufacturers and distributors of prescription opioids have extracted (and continue to make) billions of dollars in revenue from the American public off the sale of these narcotics. Meanwhile, local governments like Plaintiffs have been forced to shoulder an ever-growing share of the opioid epidemic's burdens.

72. This state of affairs could have been avoided, but for the conduct of Defendants. In their own way, each Defendant has engaged in a pattern and practice of wrongful, intentional, and unlawful conduct to push prescription opioids onto the public and into communities, in pursuit of record profits from this product line. They have done so despite knowing of the reasonably foreseeable consequence in Plaintiffs' communities and across the nation: a prescription opioid epidemic of a tragic, enormous magnitude.

II. Manufacturer Defendants Engaged In A Years' Long Campaign To Increase Opioid Sales By Misrepresenting Their Risks And Benefits.

73. The use of opioids for managing long-term, non-cancer pain is now understood to be based on "unsound science and blatant misinformation … and dangerous assumptions that opioids are highly effective and safe, and devoid of adverse events when prescribed by physicians."[36]

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[34] Nat'l Inst. On Drug Abuse, *Opioid Overdose Crisis* (last visited March 1, 2018), *available at* https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

[35] White House Council of Economic Advisers, The Underestimated Cost of the Opioid Crisis Table 3 (Nov. 2017), available at https://www.whitehouse.gov/the-press-office/2017/11/20/cea-report-underestimated-cost-opioid-crisis.

[36] Standiford Helm II, et al., *Opioid Epidemic in the United States*, 15 Pain Physician 9 (2012),

74. This was commonly understood even in the early 1990s, when opioids were commonly used to treat acute pain. As Dr. Russell Portenoy, a former pain specialist at New York's Memorial Sloan Kettering Cancer Center (and publicly an ardent promoter of opioid usage), put it in a 1994 book:

> At the present time, neither the medical literature nor clinical experience provides compelling evidence that long-term opioid use would be salutary for more than a very small number of patients with chronic nonmalignant pain….

In contrast with this statement, the prior year Dr. Portenoy—who received funding for his work from Defendant Purdue—had told the *New York Times* that opioids were a "gift from nature," ought to be destigmatized, and that concerns about addiction and abuse were a mere "medical myth" aimed at propagating hysterical "opiophobia" in the medical profession.[37]

75. In a 2012 interview with the *Wall Street Journal,* following a decade and a half of promoting opioids as an effective tool for chronic non-cancer pain relief, Dr. Portenoy admitted that his advocacy had been in error: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? … I guess I did."[38]

76. But Dr. Portenoy was far from alone in spreading this "misinformation." Manufacturer Defendants orchestrated, participated in, and benefitted from a major campaign to shift the public's and medical profession's perception of opioid use by disseminating misinformation about the efficacy and safety of long-term opioid use, while downplaying its severe risks.

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available at https://www.ncbi.nlm.nih.gov/pubmed/22786464?report.

[37] Elisabeth Rosenthal, *Patients in Pain Find Relief, Not Addiction, in Narcotics*, N.Y. Times (Mar. 28, 1993), http://www.nytimes.com/1993/03/28/us/patients-in-pain-find-relief-not-addiction-in-narcotics.html?pagewanted=all.

[38] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall. St. J. (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

77. Each Manufacturer Defendant has conducted, and has continued to conduct, marketing schemes designed to persuade doctors and patients that opioids can and should be prescribed for treating chronic non-cancer pain. This has resulted in opioids' being used to treat for a far broader group patients than would have otherwise been possible, both in Plaintiffs' communities and nationwide.

78. In connection with this scheme, each Manufacturer Defendant spent and continues to spend millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids, while overstating their benefits in treating chronic non-cancer pain.

79. Manufacturer Defendants have made false and misleading claims, often contrary to the contents of their drugs' labeling. Among other things, they have:

- Downplayed the risk of addiction;
- Created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing;
- Advocated doctors should treat the signs of addiction with more opioids;
- Downplayed the difficulty of managing opioid dependence and withdrawal;
- Denied the risks of taking increasingly higher doses of prescription opioids over time; and
- Exaggerated the efficacy of 'abuse-deterrent' opioid formulations to prevent abuse and addiction.

80. Manufacturer Defendants have repeatedly, broadly, and falsely touted the benefits of long-term opioid use, including their alleged ability to improve functioning and quality of life for chronic non-cancer pain patients, despite—as described above—a lack of any valid basis in scientifically reliable evidence.

81. These messages have been disseminated by Manufacturer Defendants directly through sales representatives, through speaker groups led by physicians specifically recruited by the Manufacturer Defendants, through unbranded, misleading marketing materials, and through

industry-funded Front Groups (with generic names like the American Pain Society).[39]

82. To say that Manufacturer Defendants' efforts have been successful (by their measure) would be a gross understatement. Opioids are now the most prescribed class of drugs in the country, with U.S. sales generating tens of billions of dollars in revenue per year for Manufacturer Defendants. In a 2016 letter to physicians across the country, then-Surgeon General Vivek H. Murthy expressly connected this success in selling opioids to "heavy marketing of opioids to doctors … [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[40]

83. But Manufacturer Defendants' success has come at tremendous costs for patients and communities across the country—including Plaintiffs.

84. Nonetheless, Manufacturer Defendants have continued on in their campaign of deception, knowing that it was causing an epidemic and the widespread harms alleged herein.

A. Manufacturer Defendants Push Junk Science And Misleading Claims About Opioids.

85. Manufacturer Defendants' marketing efforts proceeded along two tracks, serving related purposes.

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[39] *See, e.g.*, Patrick Radden Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain; Matthew Perrone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, Associated Press (Sept. 19, 2016), https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7; Maggie Fox, *Many Doctors Get Goodies from Opioid Makers*, NBC (Aug. 10, 2017) (noting that "one out of every 12 U.S. doctors gets money … or something else of value from companies that make opioid drugs"); Lynete Reid & Matthew Herder, *The Speakers' Bureau System: A Form of Peer Selling*, 7 Open Med e31 (2013); Jeffrey J. Meffert, *Key Opinion Leaders: Where They Come From and How That Affects the Drugs You Prescribe*, 22 Dermatologic Therapy 262 (2009); IMAP, Speakers' Bureaus: Best Practices for Academic Medical Centers (Oct. 10, 2013), http://bit.ly/2E1bhdd ("Speakers' bureaus may lead to the dissemination of false or biased information" due in part to the "compensation provided for these engagements.")

[40] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), *available at* http://i2.cdn.turner.com/cnn/2016/images/08/25/sg.opioid.letter.pdf.

86. First, Defendants worked through branded and unbranded marketing to build confidence in long-term opioid use by overstating its benefits and downplaying its risks. Second, Manufacturer Defendants worked through their own staffs of sales representatives, physician speakers (whom those representatives recruited), and advertisements in medical journals to claim their share of that broadened market for opioid products.

87. Manufacturer Defendants directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

88. Because Plaintiffs are mostly municipalities and entities residing in the most populous county in Illinois, Plaintiffs are an important target of Manufacturer Defendants' efforts, based on their area's population density, resultant sales efficiency, and demographics. Manufacturer Defendants employed the same marketing plans and strategies described herein in and around Plaintiffs' communities as they did across Illinois, and nationwide.[41]

89. As described herein, Manufacturer Defendants' misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic non-cancer pain were part and parcel of Defendants' deceptive marketing campaigns in Plaintiffs' communities and nationwide.

1. Manufacturer Defendants' use of deceptive marketing.

90. Manufacturer Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs.

91. Manufacturer Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists (such as the *Journal of Pain* and

[41] In the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters.

Clinical Journal of Pain) to journals with wider medical audiences (such as the *Journal of the American Medical Association*). Manufacturer Defendants' advertising budgets peaked in 2011, when they collectively spent over $14 million on medical journal advertising of opioids—nearly triple what they spent in 2001.

92. As described in detail in Section II.C below, many of these branded advertisements deceptively portrayed the benefits and risks of opioid therapy for treating chronic pain.

2. Manufacturer Defendants deceptively promoted opioids through sales representatives and self-recruited physician speakers.

93. Each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers"— sales representatives who visited individual physicians and their staff in their offices—and small group speaker programs. By establishing close relationships with doctors, Manufacturer Defendants' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings allowing them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic non-cancer pain.

94. Representatives were trained on techniques to build these relationships, with Actavis even rolling out an "Own the Nurse" kit as a "door opener" to doctor access.

95. Manufacturer Defendants have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that detailers' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits, and face-to-face detailing has the highest influence on intent to prescribe.[42]

[42] *See, e.g.,* Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 Mktg. Letters 129

96. Manufacturer Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice, Manufacturer Defendants purchased and closely analyzed prescription sales data from IMS Health that allowed them to track, precisely, the rates of initial prescribing and renewal by individual doctors. This in turn allowed them to target, tailor, and monitor the impact of their appeals to prescribe more opioids for chronic non-cancer pain treatment.

97. Manufacturer Defendants in particular relied upon "influence mapping," using decile rankings (or similar breakdowns) to identify high-volume prescribers for whom detailing could have the greatest sales impact.

98. Manufacturer Defendants also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

99. Manufacturer Defendants' sales representatives have visited hundreds of thousands of doctors, including numerous visits to prescribers in Plaintiffs' communities. As described herein, these visits were used to spread misinformation regarding the risks, benefits, and superiority of opioids for the treatment of chronic non-cancer pain.

100. Each Manufacturer Defendant carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of that company's drugs in particular and opioids in general. Pharmaceutical companies exactingly direct and monitor their

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(2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33 Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in *on*-label prescription of promoted drugs); *see also* Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 90 Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and other means—to ensure that individual detailers actually deliver the desired messages, and do not veer off-script. Pharmaceutical companies likewise require their detailers to deploy sales aids reviewed, approved, and supplied by the company (and forbid them to use, in industry parlance, "homemade bread," *i.e.*, promotional materials not approved by the company's marketing and compliance departments).

101. Sales representatives' adherence to their corporate training is typically included in their work agreements. Departing from their company's approved messaging can and does lead to severe consequences, including termination of employment.

102. In addition to making sales calls, Manufacturer Defendants' detailers also identified doctors to serve, for payment, on Manufacturer Defendants' speakers' bureaus and to attend programs with speakers and meals paid for by Manufacturer Defendants.

103. Manufacturer Defendants almost always select physicians to be speakers who are "product loyalists," since one question they will invariably be asked is whether they prescribe the drug themselves. Such invitations are lucrative to the physicians selected for these bureaus.

104. These speaker programs and associated speaker training serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, opioids; the provide a forum in which to further market prescription opioids to the speaker him or herself; and provide an opportunity to market to the speaker's peers.

105. Manufacturer Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Manufacturer Defendants also track the prescribing of event attendees.

106. Like the sales representatives who select them, speakers are expected to stay "on

message"—indeed, they agree in writing to follow the slide decks provided to them by Manufacturer Defendants. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by Manufacturer Defendants.

107. Although these speaker events are more expensive to host, and typically have lower attendance than Continuing Medical Education ("CME") courses, they are subject to less professional scrutiny. Thus, they afford Defendants greater freedom in the messages they can convey to doctors.

108. Manufacturer Defendants have devoted massive resources to these direct sales contacts with prescribers. Upon information and belief, in 2014 alone, Manufacturer Defendants collectively spent at least $168 million on detailing branded opioids to physicians nationwide. This figure includes, upon information and belief, $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis.

109. The total figure is more than double Defendants' collective spending on detailing in 2000, and includes, upon information and belief, thousands of dollars spent on detailing to doctors in and around Plaintiffs' communities.

3. Manufacturer Defendants use front groups, doctors, and unbranded marketing to push bogus opioid claims—and their products.

110. In addition to their direct marketing efforts, Manufacturer Defendants used unbranded, third-party marketing, which they deployed as part of their national marketing strategies for their branded drugs. Each Manufacturer Defendant executed these strategies through a network of third-party Key Opinion Leaders ("KOLs") and Front Groups, with which they acted in concert by funding, assisting, encouraging, and directing their efforts, while at the same time exercising substantial control over the content of these third parties' messages.

111. As with their other marketing strategies, Manufacturer Defendants' unbranded marketing created and relied upon an appearance of independence and credibility that was undeserved but central to its effectiveness. By using unbranded communications, drug companies sidestepped the extensive regulatory framework governing branded communications.

112. Manufacturer Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Manufacturer Defendants' marketing plans, which specifically contemplated their involvement because they seemed independent (and therefore outside of FDA oversight.) Through unbranded materials, Defendants presented information and instructions concerning opioids that were contrary to, or at best inconsistent with, information and instructions listed on Defendants' branded marketing materials and drug labels. This was done with Defendants' knowledge of the true risks, benefits and advantages of opioids.

113. Manufacturer Defendants did so knowing, and in reliance on the fact that, such unbranded materials are typically not submitted to nor reviewed by the FDA.

114. Even where such unbranded messages were channeled through third-party vehicles, Manufacturer Defendants adopted these messages as their own by citing to, editing, approving, and distributing such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete.

115. Moreover, Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Manufacturer Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Manufacturer Defendants exercised control over their

deceptive messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

116. The third-party publications Manufacturer Defendants assisted in creating and distributing did not include the warnings and instructions mandated by their FDA-required drug labels and consistent with the risks and benefits known to Defendants. For example, these publications either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

a. Defendants developed KOLs.

117. Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids.[43]

118. Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Defendants by touting the benefits of opioids to treat chronic pain.

119. Pro-opioid doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. KOLs have written, consulted on, edited, and lent their names to books and articles, given speeches, and led CMEs supportive of opioid therapy for chronic non-cancer pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain (while knowing of the lack of evidence to support the practice), as well as on the boards of pro-opioid advocacy groups and professional

[43] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

societies that develop, select, and present CMEs.

120. Manufacturer Defendants were able to exert control of each of these modalities through their KOLs. In return, the KOLs' association with Manufacturer Defendants provided them not only money, but prestige, recognition, research funding, and avenues to publish. This positioned the KOLs—and by association, Manufacturer Defendants—to exert even more influence in the medical community.

121. Manufacturer Defendants cited and promoted favorable studies or articles by these KOLs. In contrast, Manufacturer Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy. One prominent KOL sponsored by Defendants, the aforementioned Dr. Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding.

122. Some KOLs have even gone on to become direct employees and executives of Manufacturer Defendants, like Dr. David Haddox, Purdue's Vice President of Risk Management, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

123. Manufacturer Defendants provided substantial opportunities for KOLs to participate in research on topics Manufacturer Defendants suggested or chose, with the predictable effect of ensuring many favorable studies appeared in the academic literature. As described by KOL Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Portenoy regularly agreed to do so.

124. Manufacturer Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences. From 2000 on, Cephalon, for instance, paid doctors more than $4.5 million for programs relating to its

opioids.

125. Manufacturer Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said—as they did with all their recruited speakers, discussed above. The KOLs knew or deliberately ignored the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Defendants, all the while causing harm to prescribers and patients in Plaintiffs' communities as a result.

126. As indicated above, Dr. Russell Portenoy was a favorite Manufacturer Defendant KOL. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

127. Dr. Portenoy was instrumental in opening the door to the use of opioids to treat chronic pain. He served on the American Pain Society ("APS") and American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain—first through their widely-distributed 1997 guidelines, and again through the guidelines' 2009 version. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy group almost entirely funded by Manufacturer Defendants.

128. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this program, broadcast in Plaintiffs' communities and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric

disorder, most doctors can feel very assured that that person is not going to become addicted."

129. To his credit, Dr. Portenoy has recently admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures claimed, among other things, the Purdue-created falsehood that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks.

130. Dr. Portenoy has also conceded that "[d]ata about the effectiveness of opioids does not exist."[44]

131. Dr. Lynn Webster was another favorite KOL. Webster was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting its opioid product Opana ER.

132. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon alone).

133. Dr. Webster had been under investigation for overprescribing by the DEA, which raided his clinic in 2010. More than twenty of Dr. Webster's former patients at the Lifetree Clinic have died from opioid overdoses.

134. Dr. Webster was a leading proponent of the concept of "pseudoaddiction," a

[44] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

scientifically unproven—yet frequently touted—notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate between the two was to increase a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases … should be the clinician's first response." Endo distributed this book to doctors.

135. Years later, Dr. Webster said that "[pseudoaddiction] obviously became … an excuse to give patients more medication."[45]

136. Dr. Scott Fishman was another favored KOL, and was the author of the deceptive 2007 guide *Responsible Opioid Prescribing*, discussed below, which was paid for, in part by Manufacturer Defendants Purdue, Endo, and Cephalon.

137. Fishman's ties to the opioid drug industry are legion. Fishman was a past president of the AAPM, as well as a board member of the APF, both discussed below and referenced above. He has participated in numerous opioid-friendly continuing medical education courses for which he has received compensation by one or more Manufacturer Defendants, and helped to lobby against anti-opioid legislation.

138. Fishman himself has acknowledged his failure to disclose all of his potential conflicts of interests in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures In A Letter On Reducing Opioid Abuse and Diversion."[46]

139. There are numerous other KOLs that Manufacturer Defendants have developed and utilized over the years, including Drs. Perry G. Fine and David Haddox. These KOLs'

[45] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee J. Sentinel (Feb. 19, 2012), *available at* https://www.medpagetoday.com/neurology/painmanagement/31254.
[46] Scott M. Fishman, *Incomplete Financial Disclosures In A Letter On Reducing Opioid Abuse And Diversion*, 30 J. Am. Med. Ass'n 1445 (2011).

stories largely mirror the stories of Portenoy, Webster, and Fishman, depicting doctors eager to do Manufacturer Defendants' bidding by promoting prescription opioids for unsupported uses, in order to increase their profiles, fund their research, and, as a result, grow the market for prescription opioids.

b. Manufacturer Defendants knowingly pushed bogus "research."

140. Rather than find a way to actually test the safety and efficacy of opioids for long-term use, Manufacturer Defendants led everyone to believe that they already had.

141. Manufacturer Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to shape the perceptions of prescribers, patients and payors.

142. This information, masquerading as scientific literature, was in truth marketing material, focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

143. To accomplish this, Manufacturer Defendants—sometimes through third-party consultants or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. Manufacturer Defendants coordinated the timing and publication of manuscripts, abstracts, posters, oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs.

144. The plans for these materials did not originate in the departments within Manufacturer Defendants that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients. Rather, they came from their marketing departments, and from marketing and public relations consultants.

145. Manufacturer Defendants often relied on "data on file" publications or presentation posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed Manufacturer Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

146. Manufacturer Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study.

147. One notable example is the Manufacturer Defendants' aggressive promotion of a 1980 letter that appeared in the well-respected New England Journal of Medicine: J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 New Eng. J. Med. 123 (1980) ("Porter-Jick Letter"). The letter is cited 856 times in Google Scholar, including 86 citations since 2010. It also appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.[47] Upon information and belief, each Manufacturer Defendant has referenced the Porter-Jick Letter in their marketing materials—branded and/or unbranded—during the relevant time period.

148. Manufacturer Defendants and those acting on their behalf fail to reveal that this "article" is actually a letter to the editor, not a study. The Porter-Jick Letter describes a review of the charts of hospitalized patients who had received opioids. (Because the review was conducted in 1980, standards of care from the time almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.) The Porter-Jick Letter notes that, when these patients'

[47] AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; "Chronic Pain Management and Opioid Use," October 11, 2012, sponsored by Purdue. Each CME is available for online credit, including to prescribers in Plaintiffs' communities.

records were reviewed, it found almost no references to signs of addiction—though there is no indication that caregivers were instructed to assess or document signs of addiction.

149. None of these serious limitations is disclosed when Manufacturer Defendants or those acting on their behalf cite the Porter-Jick Letter, often as the sole scientific support for the proposition that opioids are rarely addictive even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.[48]

150. As researchers reviewing the Porter-Jick Letter's use by opioid promoters concluded, this "five-sentence letter published in … 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy [and] 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."[49]

151. Manufacturer Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. Manufacturer Defendants' studies and articles often targeted articles that contradicted Manufacturer Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Manufacturer Defendants—often with the help of third-party consultants—targeted a broad range of media to get their message out, including articles, letters to the editor, commentaries, case-study reports, and newsletters.

152. These strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief, distorting prescribing patterns as a result.

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[48] *Painful Words: How A 1980 Letter Fueled The Opioid Epidemic*, Associated Press (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

[49] German Lopez, *A 5-Sentence Letter Helped Trigger America's Deadliest Drug Overdose Crisis Ever*, Vox (June 1, 2017), https://www.vox.com/science-and-health/2017/6/1/15723034/opioid-epidemic-letter-1980-study.

c. Manufacturer Defendants push favorable treatment guidelines.

153. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors (frequent targets of Manufacturer Defendants) who are otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments.

154. Manufacturer Defendants, on a number of occasions, promoted (and helped pay for) the publication of treatment guidelines that supported a more widespread use of their prescription opioid products than contemporary science and medicine justified.

155. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States, including Illinois's Board of Professional Regulation. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

156. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB admitted was produced "in collaboration with pharmaceutical companies." The FSMB guidelines taught that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines fail to mention risks of overdose, and discuss addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

157. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines*, Responsible Opioid Prescribing*, also made these claims.

158. These guidelines were posted online and were available to and intended to reach physicians in Plaintiffs' communities that were able to prescribe opioids for their patients.

159. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for later distribution to prescribing doctors).

160. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), including, upon information and belief, Illinois'. The FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale. The FSMB website has described the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

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

162. Indeed, the FSMB actually issued a report calling on medical boards to punish doctors who inadequately treat pain.[50]

163. Although the 2012 revision of *Responsible Opioid Prescribing* continues to teach that pseudoaddiction is real and that opioid addiction risk can be managed through risk

[50] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

screening, it no longer recommends chronic opioid therapy as a first choice after the failure of over-the-counter medication. It also has heightened its addiction and risk warnings.

164. Upon information and belief, from 2001 to 2012 the FSMB received at least $820,000 in payments from Purdue; at least $370,000 in payments from Endo; at least $180,000 from Cephalon; and at least $100,000 from Mallinckrodt. Upon information and belief, this included at least $40,000 from Endo and $50,000 from Purdue to specifically fund the production of *Responsible Opioid Prescribing*.

165. In a 2012 letter to the Senate Finance Committee—which was then investigating the abuse of prescription opioids—the FSMB stated that *Responsible Opioid Prescribing* had been distributed in all 50 states and the District of Columbia.[51]

166. Similarly flawed guidelines were published by the AAPM and APS, each of which received substantial funding from Manufacturer Defendants. These organizations also issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.

167. The co-author of the AAPM-APS statement, KOL Dr. David Haddox, was at the time a paid speaker for Purdue.[52] KOL Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011, and was available to and intended to reach physicians in Plaintiffs' communities that were responsible for deciding whether to prescribe opioids to their patients.

168. AAPM and APS issued their own guidelines in 2009 ("AAPM-APS Guidelines")

[51] Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley (June 8, 2012), *available at* http://bit.ly/2tnvN65.

[52] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

and continued to recommend the use of opioids to treat chronic non-cancer pain. Fully two-thirds of the panel members—14 of 21 members—who drafted the AAPM-APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and/or Purdue.

169. The AAPM-APS Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by Manufacturer Defendants' contributions.

170. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies. The AAPM-APS Guidelines committee clearly failed to meet this standard.

171. These AAPM-APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians in Plaintiffs' communities, but also the body of scientific evidence on opioids. The Guidelines have been cited 732 times in academic literature, were—upon information and belief—disseminated in Plaintiffs' communities during the relevant time period, are still available online, and were even reprinted in the *Journal of Pain*.

172. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

173. Finally, the American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding

the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain … should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[53]

174. These recommendations, which continue to appear on AGS's website, are not supported by reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

175. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were released at the May 2009 AGS Annual Scientific Meeting in Chicago and first published online on July 2, 2009. AGS submitted grant requests to Defendants including Endo and Purdue beginning July 15, 2009.

176. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[54] Five of 10 of the experts on the guidelines panel disclosed financial ties to Manufacturer Defendants, including serving as paid speakers and consultants, presenting classes sponsored by them, receiving grants from them, and investing in their stock.

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[53] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009).

[54] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel (May 30, 2012).

d. Manufacturer Defendants relied on Continuing Medical Education programs.

177. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure.

178. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are delivered by doctors who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

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

180. In all, Manufacturer Defendants sponsored CMEs that were delivered thousands of times—including numerous CMEs attended by physicians in Plaintiffs' communities—promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

181. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in

which external interests could influence the availability and/or content" of the programs. It urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[55]

182. Dozens of CMEs that were available to and attended or reviewed by doctors in Plaintiffs' communities during the relevant time period did not live up to the AMA's standards.

183. The influence of Manufacturer Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by those who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Participants who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. Those that read the non-industry-funded CME mentioned the risks of death and addiction much more frequently. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.[56]

184. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, Manufacturer Defendants could expect messages to be favorable to them. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy.

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[55] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), *available at* https://www.ama-assn.org/delivering-care/financial-relationships-industry-continuing-medical-education.

[56] Letter from Senator Claire McCaskill to James A. Schoeneck, President and Chief Executive Officer of Depomed, at 2–3 (Mar. 28, 2017).

e. Manufacturer Defendants make use of Front Groups.

185. Defendants Cephalon, Endo, Janssen, and Purdue entered into arrangements with numerous organizations to promote opioids, including many of those identified above. These organizations depend upon Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Defendants' marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain.

186. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

187. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, AAPM, FSMB, the American Chronic Pain Association ("ACPA"), and the American Society of Pain Educators ("ASPE"). **See Figure 1.**

	Purdue[22]	Janssen[23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00[24]	$0.00	**$1,265,566.81**
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	**$1,199,409.95**
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	**$304,605.00**
ACS Cancer Action Network	$168,500.00[25]	$0.00	$0.00	$0.00	$0.00	**$168,500.00**
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	**$417,140.00**
American Geriatrics Society	$11,785.00[26]	$0.00	$0.00	$0.00	$0.00	**$11,785.00**
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	**$25,000.00**
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	**$962,724.52**
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	**$30,000.00**
American Society of Pain Management Nursing	$242,535.00	$55,177.85[27]	$25,500.00[28]	$0.00	$0.00	**$323,212.85**
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	**$163,095.00**
The National Pain Foundation[29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	**$562,500.00**
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00[30]	$0.00	**$2,922,800.00**
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	**$500,000.00**
	$4,153,554.33	**$465,152.85**	**$1,071,116.95**	**$3,146,265.00**	**$20,250.00**	**$8,856,339.13**

Figure 1.[57]

188. For years, the most prominent of Manufacturer Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue

[57] Sen. Homeland Security & Governmental Affairs Cmte, *Fueling An Epidemic: Exposing The Financial Ties Between Opioid Manufacturers And Third Party Advocacy Groups*, at 4 (Feb. 12, 2018), *available at* https://www.hsgac.senate.gov/download/fueling-an-epidemic-exposing-the-financial-ties-between-opioid-manufacturers-and-third-party-advocacy-groups.

provided the next largest sum, at $1.7 million. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others.

189. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely through opioids. All of the programs and materials were available nationally and intended to reach patients in Plaintiffs' communities.

190. APF held itself out as an independent patient advocacy organization. It often purported to engage in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. Indeed, as early as 2001, Purdue told APF that the basis of a grant it was giving the organization was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

191. In practice, APF operated in extremely close collaboration with opioid makers. On several occasions, representatives of the drug companies (often at informal meetings at Front Group conferences) suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies

would support projects conceived as a result of these communications.

192. One example of APF's activities stands out from the rest. *Exit Wounds* is a 2009 publication sponsored by Purdue and distributed by APF with grants from Janssen and Endo. It is written as the personal narrative of a military veteran, and describes opioids as "underused" and the "gold standard of pain medications" while failing to disclose the risk of addiction, overdose, or injury.

193. *Exit Wounds* notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications." It also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards." (As laid out above, the FSMB itself received support from Manufacturer Defendants during the time it created and published these guidelines.)

194. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose that opioids may cause fatal interactions with benzodiazapines, which are taken by a significant number of veterans. It is not the unbiased narrative of a returning war veteran: it is pure marketing, sponsored by Purdue, Endo, and Janssen. Yet, Janssen, for example, supported the marketing effort, despite acknowledging on the label for its opioid Duragesic that its use with benzodiazepines "may cause respiratory depression, hypotension, and profound sedation or potentially result in coma." Similar warnings accompany the labels of other Manufacturer Defendants' opioid products.

195. *Exit Wounds*' deceptive nature is obvious in comparison to guidance on opioids published by the U.S. Veterans Administration in 2010 and 2011. That guidance, *Taking Opioids*

Responsibly, describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. It also offers the list of side effects from opioids, including decreased hormones (referring to testosterone), nausea, sleep apnea, addiction, immune system changes, birth defects and death—none of which are disclosed in *Exit Wounds*.

196. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it.

197. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

198. The second most prominent of Manufacturer Defendants' Front Groups, AAPM, was similarly conflicted. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers.

199. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California (or other resort locations). AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors.

200. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council, and

presented deceptive programs to doctors who attended this annual event.

201. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOL Dr. Perry Fine and aforementioned KOLs Portenoy and Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated at the AAPM's 21st annual meeting that he would place the organization "at the forefront" of teaching that "the risks of addiction are … small and can be managed."[58]

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

203. One other vehicle for Manufacturer Defendants' collective efforts bears mentioning here: the Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goal of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the Forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

204. PCF is primarily composed of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); industry-friendly professional organizations (*e.g.,* AAPM, APS, and the American Society of Pain Educators); industry-friendly patient advocacy groups (*e.g.*, APF and ACPA); like-minded organizations (*e.g.,* FSMB); and

[58] Paula Moyer, *The Current State of Pain Management*, MedScape (2005), https://www.medscape.org/viewarticle/500829. Note that the disclaimer at the bottom of the articles states that "[t]his program was supported by an independent educational grant from Cephalon." *Id.*

doctors and nurses favorable to these other entities' messaging on prescription opioids.

205. PCF developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids, which the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients. This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would deflate Defendants' marketing efforts.

206. The recommendations—drafted by Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." As such, Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

207. Thus, like cigarette manufacturers before them, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Manufacturer Defendants worked with each other and with, and through, the Front Groups and KOLs they funded and directed, to carry out a common scheme to deceptively market the risks, benefits, and superiority of opioids to treat chronic non-cancer pain. In speeches, lectures, pamphlets, and books, Manufacturer Defendants deliberately fed misinformation about prescription opioids to the public and medical profession, which were deceived into believing the false and misleading claims.

B. The U.S. Senate Investigates, Confirming Manufacturer Defendants' Grossly Deceptive Practices.

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

209. The Senate Finance Committee sent letters to Manufacturer Defendants Purdue, Endo and Johnson & Johnson, as well as five groups that support pain patients, physicians or research, including the APF, AAPM, APS, the University of Wisconsin Pain & Policy Studies Group, and the Center for Practical Bioethics. Letters also went to the FSMB and the Joint Commission (another purveyor of industry-approved "Pain Management Standards" via opioid treatment).

210. As shown from the below 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:

> The United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful 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 "[d]ata 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.
>
> [….] 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.[59]

211. The Senators demanded substantial discovery, including payment information from the companies to many of the front organizations identified above, as well as to physicians, like KOLs Portenoy, Fishman, and Fine, among others. The reporting from this investigation has not yet been publicly released.[60]

212. On March 29, 2017, another Senate investigation into these practices was launched by Senator Claire McCaskill (D-MO). At a hearing McCaskill convened later that year, Professor Adriane Fugh-Berman, an Associate Professor at Georgetown University Medical Center, testified about Manufacturer Defendants role in sparking the opioid epidemic:

> 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 –

[59] Letter from U.S. Senators Charles E. Grassley and Ma Baucus to Eric Hauth, Executive Director, American Pain Foundation (May 8, 2012), *available at* http://bit.ly/2I7whjX.

[60] Paul D. Thacker, *Senators Hatch And Wyden: Do Your Jobs And Release The Sealed Opioids Report*, Stat News (June 27, 2016), https://www.statnews.com/ 2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/.

> comprises about five percent of the world population, but we use about two-thirds of the world supply of opioids.[61]

213. Fugh-Berman also stated why doctors were able to be convinced by Manufacturer Defendants' false and misleading 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.
>
> [….] 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 (ph) condition that's treated by increasing opioid dosages.
>
> […] 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.

214. Finally, Fugh-Berman pointed out that Manufacturer Defendants' conduct is ongoing, and that "[b]etween 2013 and 2015, one in 12 physicians took out money from opioid manufacturers, a total of $46 million. Industry-friendly messages that pharmaceutical companies

[61] *WATCH: McCaskill Leads Roundtable On Role of Drug Manufacturers In The Opioid Crisis*, PBS (Sept. 12, 2017), https://www.pbs.org/newshour/health/watch-live-mccaskill-leads-roundtable-role-drug-manufacturers-opioid-crisis.

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." She concluded: "It is a misperception to think that most opioid deaths are caused by misuse of opioids are overdoses … Misuse isn't the problem; use is the problem."

C. Specific Examples of Individual Manufacturer Defendants' Conduct.

215. As described above, Manufacturer Defendants have engaged in a long, egregiously deceptive campaign to shift public (and the medical profession's) opinion about the risks and benefits of prescription opioids for the treatment of chronic non-cancer pain (for which, as explained above, it has no proven application).

216. This conduct was a part of a unified plan, as well as engaged in individually by each Manufacturer Defendant. Representative examples of their conduct follows.

1. Purdue.

217. Purdue, perhaps more than any other Manufacturer Defendant, exemplifies its industry's deceptive approach to marketing prescription opioids since the late 1990s.

218. Purdue, which is privately held by the Sackler family, manufactures, and then markets, sells, and distributes the following Schedule II narcotics nationwide, including in Plaintiffs' communities:

- **Oxycontin (oxycodone hydrochloride extended release).** An opioid agonist meant to treat pain severe enough to require daily, around-the-clock, long-term treatment. It is not indicated as an "as-needed" analgesic. First approved by the FDA in December 1995.
- **MS Contin (morphine sulfate extended release)**. A controlled-release tablet form of morphine sulfate, indicated for severe pain management and not intended for as-needed use. First approved by the FDA in May 1987 as an opioid pain medicine allowing for dosing every twelve hours.
- **Dilaudid (hydromorphone hydrochloride)**. Injectable and oral opioid analgesic that is eight times more potent than morphine. A related medication, **Dilaudid-HP**, is a higher-potency and more concentrated formulation of the drug intended for moderate-to-severe pain relief in

opioid-tolerant patients.

- **Hysingla ER (hydrocodone bitrate**). A brand name, extended-release form of hydrocodone bitrate indicated for the management of severe pain.
- **Targiniq ER.** A brand name, extended release combination of oxycodone hydrochloride and naloxone hydrochloride. First approved by the FDA on July 23, 2013.[62]

219. Before Purdue launched its flagship opioid brand Oxycontin in 1996, opioids were typically used to treat severe short-term pain, except for in terminally ill patients. This was because, as indicated above, the medical community was aware of both the risks of opioids and the relative ineffectiveness of their long-term use in treating most forms of chronic pain. The conventional wisdom was that opioids would appear effective in the short term, but prove ineffective over time with increasingly negative, dire side effects (including addiction).

220. So when Purdue launched Oxycontin, it sought to broaden its use to treating most or all forms of chronic pain—including back pain, arthritis, and headaches. This plan had the benefit of producing a more sustained revenue stream for Purdue, in light of the greater frequency of those maladies. But the company hit a snag: doctors were too worried about the risk of patients becoming addicts (or worse) to give them prescription opioids for these illnesses.

221. As such, Purdue set out to—and did—convince doctors that while opioids *were* potentially addictive, patients with legitimate pain who remained under a doctor's supervision would not become addicted, and that the overall risk of addiction extremely low. The methods and means by which Purdue accomplished this are multi-faceted.

a. Purdue falsely marketed extended-release drugs as safer and more effective than regular-release drugs.

222. Purdue launched OxyContin 20 years ago with a powerful, bold claim: "One dose

[62] An "agonist" medication is one that binds to and fully activates targeted receptors in the brain. They activate these neurotransmitter receptors to elicit a certain response. An "antagonist" medication, conversely, works to prevent the binding of other chemicals to neurotransmitters in order to block a certain response.

relieves pain for 12 hours, more than twice as long as generic medications."[63] Purdue told doctors in its Oxycontin press release that a single tablet would provide "smooth and sustained pain control all day and all night."

223. In large part because of these promises, the nationwide marketing campaign to promote it, and Purdue's repeated assurances that opioids were both effective and largely non-addictive, Oxycontin became America's bestselling painkiller.

224. Purdue's nationwide marketing claims were highly deceptive. OxyContin was not superior to immediate-release opioids. And not only does Oxycontin wear off earlier than 12 hours, as Purdue's own studies showed, but it is highly addictive.

225. A *Los Angeles Times* investigation of Oxycontin reviewed thousands of pages of confidential Purdue documents, court records, emails, memoranda, meeting minutes and sales reports, spanning three decades from the conception of Oxyocontin in the mid-1980s to 2011. It also reviewed sworn testimony by Purdue executives, sales representatives, and other employees. The investigation found that:

- Purdue knew for decades that it was falsely promising 12-hour pain relief from Oxycontin;
- Even before going to market, Purdue's clinical trials showed many patients were not getting 12 hours of relief;
- Purdue was repeatedly confronted with complaints from doctors, researchers, and reports from its own sales representatives and independent research about the substance of the 12-hour relief claim, but broadly ignored these complaints;
- Purdue maintained and mobilized a team of hundreds of sales representatives to "refocus" physicians across the country, on 12-hour dosing, despite a lack of evidence behind it;
- Purdue told doctors to prescribe stronger and stronger doses of Oxycontin for patients who continue to complain of pain, and/or become tolerant (even though this approach created a greater possibility of addiction, overdose, and death); and

[63] Harriet Ryan, et al., *"You Want A Description Of Hell?", Oxycontin's 12-Hour Problem*, L.A. Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

- Purdue's motivation behind these acts and omissions was, in large part, to protect and grow its revenue, because without the 12-hour claim Oxycontin would have little advantage over less expensive painkillers on the market.[64]

226. Reporting by the *New York Times* confirmed many of these claims, including that "internal Purdue 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." To combat this resistance, Purdue knowingly and falsely promised a long-acting, extended release formulation of Oxycontin as safer and "less prone to such problems."[65]

227. Purdue's sales culture, including in Plaintiffs' communities, was one that mandated opioids be aggressively sold, embracing a sell-at-any-cost notion. Aggressive quotas were put in place of opioids, including OxyContin, at all dosage levels, as well as Hysingla products. The highest dosage for OxyContin was even referred to by Purdue sales representatives as "hillbilly heroin."

228. When sales representatives failed to meet their quotas, they were placed on performance employment plans and/or terminated. When they were successful, they were richly rewarded with extravagant bonuses and prizes.

b. Purdue falsely marketed a low addiction risk to prescribing physicians across the country.

229. In addition to pushing Oxycontin as safe and non-addictive by equating extended-release with a lower risk of addiction and abuse, Purdue also promoted the use of prescription opioids for use in non-cancer patients and non-acute pain patients, who now make up 86 percent

[64] Harriet Ryan, et al., *Full Coverage: Oxycontin Investigation*, L.A. Times (2016), http://www.latimes.com/projects/la-me-oxycontin-full-coverage/.

[65] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.

of the total prescription opioid market.[66]

230. Rather than target physicians prescribing opioids for understood, scientifically-supported uses, Purdue heavily promoted Oxycontin nationwide and in Plaintiffs' communities for unsupported uses, and targeted doctors such as general practitioners, who often had little training in treating serious pain or recognizing the signs of drug abuse in patients.[67]

231. Purdue sales reps accomplished this in part by plying these physicians with coupons redeemable for a 7- to 30-day supply of Oxycontin—a Schedule II narcotic that cannot be prescribed for more than one month at a time—and an accompanying promise that the drug was safe. It "trained its sales rep[s] to carry the message that the risk of addiction was 'less than one percent,'" and systematically minimized the risk of addiction in the use of opioids for treating chronic non-cancer pain.[68]

232. Even as late as 2015, Purdue reps were telling physicians that OxyContin was "addiction resistant" and utilized "abuse-deterrent technology." This was wildly untrue.

233. Purdue tracked physicians' prescribing practices by reviewing pharmacy prescription data it obtained from IMS Health, a company that buys bulk prescription data from pharmacies and resells it to drug makers for marketing purposes. Purdue also could identify physicians writing large numbers of prescriptions, and particular for its high-dose 80 mg pills—potentially signs of diversion, drug dealing, and/or abuse.[69]

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[66] Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down As Senators Launch Investigation Of Prescription Narcotics*, ProPublica (May 8, 2012), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

[67] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.

[68] Art Van Zee, *The Promotion And Marketing of* Oxycontin, 99 Am. J. Pub. Health 221 (2009).

[69] An 80 mg tablet of Oxycontin is equal in strength to 16 Vicodin tablets. While generally reserved for patients with severe chronic pain who had developed a tolerance to lower dosages, "80s" were the most in-demand form on the painkiller in the illegal drug trade. For those

234. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from its sales reps, and, in some cases, its own investigations.[70] Since 2002, Purdue maintained a confidential roster of suspected reckless prescribers known as "Region Zero." By 2013, there were over 1,800 doctors in Region Zero—but Purdue had reported fewer than one-tenth of them to authorities.

235. Pursuant to the *Los Angeles Times* investigation, 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."[71]

c. Purdue funded publications and presentations with false and misleading messaging.

236. Purdue's false marketing scheme did not end with its own sales reps and branded marketing materials, but engaged third parties (including KOL doctors and Front Groups) to spread the false message of their prescription opioids' safety and efficacy.

237. Purdue caused the publication and distribution of false and deceptive guidelines

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attempting to detect OxyContin getting to the black market, a physician writing a high volume of 80 mg prescriptions would have been an obvious red flag. Harriet Ryan, et al., *More Than 1 Million OxyContin Pills Ended Up In The Hands Of Criminals and Addicts: What The Drugmaker Knew*, L.A. Times (July 10, 2016), http://www.latimes.com/ projects/la-me-oxycontin-part2/.

[70] 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. Bill Fallon, *Purdue Pharma Agrees To Restrict Marketing Of Opioids*, Stamford Advocate (Aug. 25, 2015), http://bit.ly/2tdYNx9.

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

on opioid prescribing. 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.

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

239. Similarly, multiple videos feature the KOL Dr. Perry 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, too, suggesting that it may take four or five switches over a person's "lifetime" to manage pain. 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."

240. The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." Haddox even suggests 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."[72]

241. Purdue also deceptively marketed the use of opioids for chronic pain through the

[72] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI; Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down As Senators Launch Investigation Of Prescription Narcotics*, ProPublica (May 8, 2012), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

APF, which was shut down after the U.S. Senate launched its investigation in 2012. In 2010 alone, the APF received 90 percent of its funding from drug and medical device companies, including Purdue, which gave it as much as $499,999 in 2010.

d. Purdue's conduct catches up to it.

242. 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 risks of addiction. Purdue was ordered to pay $600 million in fines and fees.

243. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. It pled guilty to illegally misbranding OxyContin in an effort to mislead physicians and consumers.

244. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines. Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines. And Paul D. Goldenheim, Purdue's former medical director, pled guilty as well and agreed to pay $7.5 million in fines. Specifically, Friedman, Udell, and Goldenheim pled guilty to a misdemeanor charge of misbranding Oxycontin and introducing such misbranded drugs into interstate commerce.

245. In a statement announcing the pleas, John Brownlee, the U.S. Attorney for the Western District of Virginia, said that while Purdue "claimed it had created the miracle drug …. 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 … OxyContin was the child of marketeers and bottom line financial decision making."[73]

[73] John Brownlee, U.S. Attorney for the Western District of Virginia, Statement of United States

246. Brownlee characterized Purdue's criminal activities 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.

247. If these activities seem familiar it may be because even after the guilty pleas, Purdue continued paying doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic non-cancer pain, and continued to fund deceptively neutral organizations to disseminate their favored talking points: opioids were highly effective, largely non-addictive, and largely safe for treating chronic non-cancer pain.

248. Purdue also continued making thousands of payments to physicians nationwide,

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Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), *available at* http://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf.

including to doctors in Plaintiffs' communities, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

249. Meanwhile, data collected by ProPublica shows that Illinois doctors prescribed over $18 million of Oxycontin in 2015 through the Medicare Part D program alone, and, upon information and belief, tens of millions of dollars' worth through private insurance. This included, upon information and belief, hundreds of thousands of dollars' worth of OxyContin and other Purdue-manufactured opioids prescribed by doctors in Plaintiffs' communities.

2. Cephalon.

250. Cephalon manufactures, and then markets, sells and distributes the following Schedule II opioids nationwide, including in Plaintiffs' communities:

- **Actiq (fentanyl citrate)**. An opioid analgesic and oral lozenge containing fentanyl citrate, which is 80 times more potent than morphine.[74] Indicated only for the treatment of breakthrough pain in cancer patients (*i.e.*, pain that "breaks through" medication otherwise effective to control pain") aged 16 and older. Approved by the FDA in 1998 with restrictions on distribution.
- **Fentora (fentanyl buccal)**. Rapid-release tablet for breakthrough pain in cancer patients. Approved by the FDA in 2006.
- **Generic Oxycodone Hydrochloride**. Another opiate agonist.

251. Because of the particular dangers posed by Actiq, in particular, the FDA specifically limited its distribution to cancer patients only, and only those "with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

252. Further, the FDA explicitly stated that Actiq "must not be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could

[74] John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292.

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." The FDA also required Actiq to be provided *only* in compliance with a strict risk-management program, limiting the drug's direct marketing to the approved target audiences: oncologists, pain specialists, and their nurses and office staff.[75]

253. In October 2000, Cephalon acquired the worldwide rights to Actiq and begin selling it in the United States. Cephalon later purchased the rights to Fentora, an even faster-acting fentanyl tablet formulation, and submitted a new application to the FDA in 2005. In September 2006, Cephalon was approved to sell Fentora but—concerned about its power and risks—the FDA limited its approval to treating breakthrough cancer pain already tolerant to opioid therapy. Cephalon began marketing and selling Fentora one month later.

a. Cephalon aggressively marketed a cancer pain drug to physicians who do not treat cancer.

254. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for growing revenue. So to increase its revenue and market share, Cephalon needed to find a broader audience, and thus began marketing its drug 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, and anesthesiologists. This included, upon information and belief, doctors of those types in and around Plaintiffs' communities.

255. According to "[d]ata gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales

[75] John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292.

representatives' visits to non-oncologists to pitch Actiq increased sixfold between 2002 and 2005. Cephalon representatives would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each coupon was good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer patients.[76]

256. 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." By 2005, Actiq's sales total had jumped to $412 million, making the drug—though approved for only a narrow customer base—Cephalon's second-bestselling pharmaceutical. By the end of 2006, Actiq's sales had exceeded $500 million.[77]

257. 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."[78]

b. Cephalon is found to have falsely marketed Actiq for off-label uses.

258. 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 the U.S. Department of Health and Human Services,

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[76] John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292.

[77] John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292; Cephalon, Inc. Annual Report (Form 10-K), at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.

[78] John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292.

agreeing to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq (as well as two non-opioid drugs, Gabitril and Provigil).

259. According to a Department of Justice 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 CMEs 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 promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results.[79]

260. Upon information and belief, the government's investigation uncovered documents confirming that Cephalon directly targeted non-oncology practices and pushed its sales reps to market Actiq for off-label uses. Specifically, it found documents demonstrating Cephalon: (1) instructed sales representatives to give physicians free Actiq coupons even if they said they did not treat patients with cancer pain; (2) targeted neurologists in order to encourage them to prescribe Actiq for the treatment of migraines; (3) had (and knew that) sales representatives utilizing outside pain management specialists to pitch Actiq, who would falsely inform physicians that Actiq does not cause a 'high' in patients and carries a low risk of diversion; (4) set sales quotas that could not have been met merely by promoting it for the drug's approved uses; (5) promoted using higher doses of Actiq than patients required; and (6) funded and controlled CME seminars that promoted and misrepresented the efficacy of the drug for off-

[79] Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing (Sept. 29, 2008), https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf

label uses, such as treating migraine headaches and for non-opioid-tolerant patients.[80]

261. Yet this had little, if any, impact on Cephalon. It continued with its deceptive marketing strategy for Actiq and Fentora in the years to come.

c. Cephalon focused on non-cancer treating physicians in falsely marketing Fentora.

262. Fentora, like Actiq, was indicated to treat only breakthrough cancer pain. But from the time it 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 misinformation campaign about the safety and non-addictiveness of Fentora, specifically, and prescription opioids, generally. In fact, Cephalon targeted many of the same doctors that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

263. During an investor earnings call shortly after Fentora's launch, Cephalon's CEO described the "opportunity" presented by Fentora for sales to non-cancer pain-treating doctors:

> 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 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 bigger field force presence, the opportunity that Fentora represents is enormous.

[80] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J. (Nov. 21, 2006), https://www.wsj.com/articles/SB116407880059829145.

d. The federal government warns Cephalon again about marketing Fentora for off-label uses, and Cephalon refuses to listen.

264. 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 that death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain."[81]

265. 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 breakthrough pain. 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.[82]

266. 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. 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.

267. 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

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[81] Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformation forPatientsandProviders/ ucm051273.htm

[82] *FENTORA® (fentanyl buccal tablet) CII*, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee, U.S. Food & Drug Administration (May 6, 2008), https://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf.

misleading because it deceptively to broadened "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora … when this is not the case." Rather, Fentora was only indicated for those who were already opioid tolerant. The FDA further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

268. Flagrantly disregarding the FDA's refusal to approve Fentora for chronic non-cancer pain 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.

269. For example, on January 13, 2012, Cephalon published an insert in the periodical *Pharmacy Times* titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite repeated warnings of dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert says: "*It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain*."[83]

e. Cephalon funded false publications and presentations.

270. In addition to its direct marketing efforts, Cephalon indirectly marketed its prescription opioids 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 non-cancer pain, that they were non-addictive, and that they were woefully under-prescribed to the detriment of patients who were needlessly suffering.

271. It did so by sponsoring pro-opioid Front Groups, misleading prescription

[83] An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Bucall Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate), *Pharmacy Times* (Jan. 13, 2012), http://www.pharmacytimes.com/ publications/issue/2012/january2012/r514-jan-12-rems).

guidelines, articles and CMEs, and paying physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

272. Cephalon sponsored numerous CMEs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians in Plaintiffs' communities and across the country.

273. For example, a 2003 Cephalon-sponsored CME presentation titled "Pharmacologic Management of Breakthrough or Incident Pain" and posted on Medscape in February 2003, instructed viewers that that:

> [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.[84]

274. 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

[84] Michael J. Brennan, et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, (last visited Mar. 1, 2018), *available at* https://www.medscape.org/viewarticle/449803.

pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[85] The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process.

275. Nowhere in the CME was cancer or cancer-related pain even mentioned.

276. Dr. Stephen H. Landy ("Landy") authored a 2004 CME available on Medscape titled "Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache 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."[86]

277. Based on an analysis of publicly available data, Cephalon paid Landy approximately $190,000 in 2009–2010 alone, and tens of thousands of dollars in the years that followed.

278. 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."[87] The article purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain, and produces dosing guidelines for 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)-

[85] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, (last visited Mar. 1, 2018), *available at* https://www.medscape.org/viewarticle/461612.

[86] *See* Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series*, 44 Headache 8 (2004).

[87] Gerald M. Aronoff, et al., *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6 Pain Med. 305 (Aug. 2005).

> 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.

279. Deeper into the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing *"[t]here 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:

> […] 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 well.

280. Through its sponsorship of the FSMB's *Responsible Opioid Prescribing: A Physician's Guide*, 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."

281. Cephalon also disseminated its false messaging through speakers' bureaus and publications. For example, at an AAPM annual meeting held February 22–25, 2006, Cephalon sponsored a presentation by KOL Dr. Webster 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, promising to show that "[i]nterim results of this study suggest [fentanyl] is safe and well-tolerated in patients with chronic pain and BTP."

282. 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*, published in *Pain Medicine*, physicians paid by Cephalon (including KOL Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of BTP to the chronic, non-cancer setting.[88] 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%).

283. The article cites the ever-present KOL Dr. Portenoy and recommends fentanyl for non-cancer patients with breakthrough pain:

> In summary, BTP [breakthrough pain] appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on [quality of life]. 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, [quality of life] assessment tools.

284. Cephalon also sponsored, through an educational grant, the regularly published journal Advances in Pain Management. An example 2008 issue of the journal shows there are

[88] 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 Pain Med. 281 (Mar. 2007).

numerous articles from KOLs like Dr. Portenoy, Dr. Webster, Dr. Steven Passik, and Dr. Kenneth L. Kirsh, all advancing the safety and efficacy of opioids. In the introductory editorial, entitled *Treatment of Pain with Opioids and the Risk of Opioid Dependence: the Search for a Balance*, the editor expresses disdain for the prior 20 years of "opioid phobia."

285. 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."[89]

286. Cephalon sponsored another CME written by KOL Dr. 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 CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain than pure opioid analgesics because of dose limitations on the non-opioid component.[90]

287. KOL Dr. Perry Fine authored a Cephalon-sponsored CME titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with Drs. Christine A. Miaskowski and Michael J. Brennan.[91] Cephalon paid to have this CME published in a "Special Report"

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[89] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2 Advances in Pain Management 9 (2008).

[90] Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape (last visited Mar. 1, 2018), *available at* http://www.medscape.org/viewarticle/563417.

[91] Perry G. Fine, et al., *Long-Term Safety And Tolerability Of Fentanyl Buccal Tablet For The*

supplement of the journal Pain Medicine News in 2009. The CME 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 breakthrough pain," including the use of fentanyl.

288. The CME purports to analyze the "combination of evidence- and case-based discussions" and ultimately concludes that:

> 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.

289. In November 2010, Dr. Perry 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." The article acknowledges that: (a) "[t]here 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" of opioids 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, incredibly, *(c) that those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."*[92]

Treatment Of Breakthrough Pain In Opioid-Tolerant Patients With Chronic Pain: An 18-Month Study, 40 J. Pain Symptom Mgmt. 747 (2010).

[92] 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*

290. Along with Purdue, Cephalon sponsored the APF's guide warning against a purported under-prescribing of opioids, which taught addiction is rare and suggested opioids have "no ceiling dose," making them the most appropriate treatment for severe pain.

291. Cephalon was also one of several opioid manufacturers who paid 14 of 21 panel members responsible for drafting the 2009 American Pain Society and American Academy of Pain Medicine opioid treatment guidelines, described above.

292. Finally 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.[93] (A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of breakthrough cancer pain 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."[94])

293. Broadly, Cephalon has paid doctors—including Portenoy, Webster, Fine, Passik, Kirsh, Landy, and others—nationwide millions of dollars since 2000 for programming and content relating to its opioids, many of whom were not oncologists nor treated cancer pain. Cephalon has also made thousands of payments to physicians nationwide, including to physicians in Plaintiffs' communities, for activities including participating on speakers' bureaus, providing consulting services, and other services.

294. Meanwhile, data collected by ProPublica shows that Illinois doctors prescribed

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Study, 40 J. Pain & Symptom Management 747 (Nov. 2010).

[93] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J. (Nov. 21, 2006), https://www.wsj.com/articles/SB116407880059829145.

[94] Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, 2012 Patient Preference and Adherence 465 (June 2012).

over $600,000 worth of Fentora in 2015 through the Medicare Part D program alone, and, upon information and belief, millions of dollars' worth of Fentora and Actiq through private insurance. Upon information and belief, doctors in Plaintiffs' communities have written prescriptions for hundreds of thousands of dollars' worth of Cephalon's prescription opioid products since their release.

3. Janssen.

295. Janssen manufactures, and then markets, sells, and distributes the following Schedule II narcotics nationwide, including in Plaintiffs' communities:

- **Duragesic (fentanyl)**. Opioid analgesic in the form of a skin patch containing a gel form of fentanyl, delivered at a regulated rate for up to 72 hours. First approved by the FDA in August 1990.
- **Nucynta (tapentadol hydrochloride)**. An immediate-release opioid agonist for the management of moderate to severe *acute* pain.
- **Nucynta ER**. An extended-release version of Nucynta, indicated for severe pain.

296. Janssen introduced Duragesic to the market in late 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 and sells Nucynta, which was first approved by the FDA in 2008. It was formulated in tablet form and in an oral solution, and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older."

297. Additionally, Janssen markets Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, Nucynta ER 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."

298. Janssen sold Nucynta and Nucynta ER to the company Depomed in 2015 for $1.05 billion.

a. The FDA tells Janssen: your ads are deceptive.

299. 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. 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."

300. 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*.[95]

301. The 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 beyond what it was approved for:

> You present the claim, "It's not just for end stage cancer anymore!" This claim suggests that Duragesic can be used for any

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

> 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.

302. Finally, the March 30, 2000 letter states 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.

303. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter about 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."

304. The September 2, 2004 letter warned Janssen regarding the company's claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. DAWN was a public health surveillance system—discontinued in 2011—that monitored drug-related visits to hospital emergency rooms and drug-related deaths. The letter stated Janssen's claim about low reported mentions was false or misleading because it

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. [I]t 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.[96]

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

- "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."

[96] 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).

- "Significant improvement in social functioning."

306. In addition, the September 2, 2004 letter identifies "*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 included "'[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 states: "Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."

307. 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 the company Mylan N.V. 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.[97]

308. Regardless, even after receiving these letters, Janssen instructed sales representatives—including those in Illinois—to market Duragesic as having better efficacy, better tolerability and better patient compliance because it was a patch instead of a pill. Illinois sales representatives were instructed, upon information and belief, to tell doctors that the patch provided better control in the event of patient opioid abuse because patients could not increase the patch dosage. However, sales representatives were aware of patients who increased the

[97] Katrina Woznicki, *FDA Issues Warning On Fentanyl Skin Patch*, MedPageToday (July 15, 2015), https://www.medpagetoday.com/productalert/prescriptions/1370.

dosage by applying more than one patch at a time and were also aware that some patients abused the patch by freezing, then chewing on it.

309. Upon information and belief, Janssen sales representatives were told that information about the manner in which certain patients abused Duragesic patches was not what the company wanted to focus on in communications with doctors.

b. Janssen funded false publications and presentations.

310. Despite these repeated warnings, Janssen continued to falsely market the risks of its prescription opioids. In 2009, PriCara, a "Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.," sponsored a brochure entitled "Finding Relief: Pain Management for Older Adults" that was 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*.

311. 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.[98]

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

> Opioid Myths
>
> Myth: Opioid medications are always addictive.
> Fact: Many studies show that opioids are rarely addictive when

[98] *Finding Relief: Pain Management for Older Adults* (2009).

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 increases over time.

313. Among the "Partners" listed in "Finding Relief: Pain Management for Older Adults" are the Front Groups AAPM and AGS, both of which have received funding from Janssen.

314. 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."[99] 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."[100]

315. Further, the website states that "many patients often develop tolerance to most of the opioid analgesic-related side effects," and repeats the scientifically unsupported discussion of "pseudoaddiction" as "a syndrome that causes patients to seek additional medications due to

[99] Prescribe Responsibly, *Legal Notice* (last visited Mar. 1, 2018), http://www.prescribe responsibly.com/legal-notice.

[100] Prescribe Responsibly, *Use of Opioid Analgesics in Pain Management* (last visited Mar. 1, 2018), http:// www.prescriberesponsibly.com/articles/opioid-pain-management.

inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases."[101]

316. Janssen has, like the other Manufacturer Defendants, made thousands of payments to physicians nationwide, including to physicians in Plaintiffs' communities, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

317. According to data collected by ProPublica, in 2015, Illinois doctors prescribed over $750,000 worth of Duragesic, more than $850,000 worth of Nucynta and more than $900,000 worth of Nucynta ER to patients insured by Medicare Part D alone, and, upon information and belief, millions of dollars' worth of these drugs through private insurance. Upon information and belief, doctors have prescribed hundreds of thousands of dollars' worth of Janssen's opioid products in Plaintiffs' communities since they were put on the market.

4. Insys.

318. Insys was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur "known for applying aggressive marketing tactics and sharp price increases on older drugs."[102]

319. Insys manufactures, and then markets, sells, and distributes the Schedule II narcotic and fentanyl spray Subsys nationwide, including in Plaintiffs' communities. Subsys was first approved by the FDA in 2012.

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[101] Prescribe Responsibly, *Use of Opioid Analgesics in Pain Management* (last visited Mar. 1, 2018), http:// www.prescriberesponsibly.com/articles/opioid-pain-management; Prescribe Responsibly, *What a Prescriber Should Know Before Writing the First Prescription* (last visited Mar. 1, 2018), http://www.prescriberesponsibly.com/articles/before-prescribing-opioids.

[102] Joseph Walker, *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall St. J. (Nov. 22, 2016), https://www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968.

320. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age or older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain."[103] The indicate 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."

321. 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' Subsys total gross sales are made through Distributor Defendants.

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

323. 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, neck pain and other off-label pain conditions. Moreover, as of June 2012, Insys defined breakthrough pain 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 the KOL Dr. Portenoy.

[103] 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."

324. 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.

325. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists.[104] Approximately half the prescriptions were written by pain specialists, with others written by other specialists including dentists and podiatrists.

a. Insys executives indicted.

326. 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.[105]

327. 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. 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

[104] Katie Thomas, Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller, N.Y. Times (May 13, 2014), https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html.

[105] Press Release, U.S. Attorney's Office for the District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme (Dec. 8, 2016), https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme; United States v. Babich, et al., No. 1:16-cr-10343-ADB, Dkt. No. 1 (D. Mass. Dec. 6, 2016), https://www.justice.gov/usao-ma/press-release/file/916681/download.

that they were calling "on behalf of" the doctor. The activities of the "reimbursement unit" are detailed further below.

328. In a superseding indictment for the same activity, the defendants are Insys' former CEO and president, former vice president of sales, former national director of sales, former vice president of managed markets and several former regional sales directors. The charges 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.

329. 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.

b. Insys targeted physicians who do not treat cancer, and funded false publications and presentations.

330. Insys targeted and bribed practitioners in an alleged 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.

331. The indictment alleges that 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.

332. The indictment alleges that 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.

333. Moreover, the executives are charged with targeting practitioners who prescribed Subsys not only for cancer pain, but for all pain. One such prescriber, Dr. Gavin Ira Awerbuch, a neurologist based in Saginaw, Michigan, was arraigned in 2014 in the Eastern District of Michigan on charges that he prescribed Subsys outside of legitimate medical indications. According to the complaint against him, Awerbuch was responsible for approximately 20.3 percent of the Subsys prescribed to Medicare beneficiaries nationwide January 2009 through January 2014. During that time, Insys' top sales representative, Brett Szymanski, earned up to $250,000 per quarter covering only Awerbuch. Awerbuch entered into a plea agreement on November 8, 2016.

334. As set forth in the indictment, at one national speakers' bureau in or about 2014, Insys' 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.

335. The indictment also alleges that, when agents of insurers or pharmacy benefit managers asked if a patient was being treated for breakthrough pain 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)."

336. The indictment alleges that Insys' 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.

337. In a press release announcing the charges, 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."

338. Insys also made thousands of payments to physicians nationwide, including to physicians in Plaintiffs' communities, for activities including participating on speakers' bureaus, providing consulting services, and other services.

339. These payments paid off, with data from ProPublica showing that Illinois doctors prescribed over $2.6 million of Subsys in 2015 through the Medicare Part D program, and, upon information and belief, millions of dollars' worth through private insurance. Upon information and belief, doctors in Plaintiffs' communities prescribed hundreds of thousands of dollars' worth of Subsys since the drug's release.

c. *Insys circumvented the prior authorization process for dangerous drugs to boost its sales.*

340. As stated, the FDA first approved Subsys for sale to the public in 2012. However, Insys encountered significant obstacles due to insurers employing a process known as prior authorization. Prior authorization prevents the over-prescription and abuse of powerful and expensive drugs. The prior authorization process requires "additional approval from an insurer or its pharmacy benefit manager before dispensing [drugs]" and may also impose step therapy which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach.[106]

341. Insys circumvented this process by forming a prior authorization unit, known at one point as the Insys Reimbursement Center ("IRC"), to facilitate the process using aggressive

[106] Senate Permanent Subcommittee on Investigations, *Combatting the Opioid Epidemic: A Review of Anti-Abuse Efforts in Medicare and Private Health Insurance Systems*, at 21 (2016), http://bit.ly/2tjIUVL; *see also* Department of Health and Human Services, Centers for Medicare & Medicaid Services, *How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage Use Pharmacies, Formularies, & Common Coverage Rules* (May 2017), https://www.medicare.gov/Pubs/pdf/11136-Pharmacies-Formularies-Coverage-Rules.pdf.

and deceptive and marketing techniques. Insys published education articles that praised their products' non-addictive nature, and funded patient advocacy groups who unknowingly promoted Insys' agenda of raising the profile of pain so that drugs could be prescribed to treat it. Further, Insys' former sales representatives, motivated by corporate greed, paid off medical practitioners to prescribe Subsys in spite of any medical need.[107] Insys employees were pressured internally and received significant monetary incentives to increase the rate of prescription approvals.[108]

342. According to a federal indictment and Senator McCaskill's ongoing investigation, IRC employees pretended to be with doctors' offices and falsified medical histories of patients in order to get insurance company approval for Subsys.[109] The report, acquired by McCaskill's investigators, includes transcripts and an audio recording of employees implementing these techniques in order to obtain authorization from insurers and pharmacy benefit managers.

343. The transcript reveals an Insys employee pretending to call on behalf of a doctor and inaccurately describes the patient's medical history. Insys employees would create the impression that the patient had cancer, without explicitly saying so, because cancer was a requirement for prior clearance to prescribe Subsys.

344. Insys was warned by a consultant that it lacked needed policies for governing

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[107] Linette Lopez, *It's Been A Brutal Week For The Most Shameless Company In The Opioid Crisis – And It's About To Get Worse*, Bus. Insider (July 12, 2017), http://www.businessinsider.com/opioid-addiction-drugmaker-insys-arrests-justice-department-action-2017-7.

[108] Roddy Boyd, *Murder Incorporated: Insys Therapeutics, Part 1*, Southern Investigative Reporting Foundation (Dec. 3, 2015), http://sirf-online.org/2015/12/03/murder-incorporated-the-insys-therapeutics-story/; *see also* Indictment, *United States v. Babich, et al.*, No. 1:16 CR 10343 (D. Mass Dec. 6, 2016), *available at* https://www.justice.gov/usao-ma/press-release/file/916681/download.

[109] Sen. Homeland Security & Governmental Affairs Cmte, *Fueling An Epidemic: Exposing The Financial Ties Between Opioid Manufacturers And Third Party Advocacy Groups*, at 7–10 (Feb. 12, 2018), *available at* https://www.hsgac.senate.gov/download/fueling-an-epidemic-exposing-the-financial-ties-between-opioid-manufacturers-and-third-party-advocacy-groups.

such activities, but the executives failed to implement corrective internal procedures. Upon information and belief, Insys' management was aware that only 10 percent of prescriptions approved through its prior authorization unit were for cancer patients—indeed, an Oregon Department of Justice investigation found that 78 percent of Insys-submitted preauthorization forms for Oregon patients were for off-label uses of Subsys.[110]

345. In an internal presentation dated 2012 entitled "2013 SUBSYS Brand Plan," Insys identified one of six "key strategic imperatives" as "Mitigate Prior Authorization barriers."[111] On a later slide, the company identified several tasks associated with this effort, including "Build internal [prior authorization] assistance infrastructure," "Establish an internal 1-800 reimbursement assistance hotline," and "Educate field force on [prior authorization] process and facilitation."

346. Documents suggest, however, that Insys did not match these efforts with sufficient compliance processes to prevent fraud, and was internally aware of the dangers involved with its practices.

347. Specifically, on February 18, 2014, Compliance Implementation Services (CIS)—a healthcare consultant—issued a draft report to Insys titled, "Insys Call Note, Email, & IRC Verbatim Data Audit Report." The introduction to the report explained that "CIS was approached by INSYS' legal representative … on behalf of the Board of Directors for Insys to request that CIS support in review of certain communications with Health Care Professionals (HCPs) and INSYS employees, and report how there were being documented." Insys had expressed concerns

[110] Dina Gusovsky, *The Pain Killer: A Drug Company Putting Profits Above Patients*, CNBC (Nov. 4, 2015), https://www.nbcnews.com/business/business-news/painkiller-drug-company-putting-profits-above-patients-n457511.

[111] U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling An Epidemic: Insys Therapeutics and the Systemic Mnupulation of Prior Authorization* (Sept. 1, 2017), http://bit.ly/2HbS5d4.

"with respect to communications with HCPs by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements." An additional concern "stemmed from the lack of monitoring of commercial activities where these types of interactions could occur."[112]

348. Given these issues, Insys requested that CIS review—in part—"the general communications from the INSYS Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers … to ensure they were appropriate in nature with respect to specific uses of SUBSYS, INSYS' commercially marketed product."

349. According to the findings CIS issued, Insys lacked formal policies governing the actions of its prior authorization unit. For example, "[n]o formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, [health care insurers (HCIs)], or patients exists…that governs the support function of obtaining a prior authorization for the use of SUBSYS."

350. In addition, the report noted that "there were also gaps in formally approved foundational policies, procedures, and [standard operating procedures] with respect to required processes specifically within the IRC." In fact, "[t]he majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast."

351. The report also explains that Insys lacked procedures for auditing interactions

[112] U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling An Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization*, at 4–5 (Sept. 1, 2017), http://bit.ly/2HbS5d4.

between IRC employees and outside entities. According to CIS, "no formal, documented, or detailed processes by which IRC representatives' calls via telephone were audited for proper communication with HCPs or HCIs in any fashion [existed] other than random physical review of a call in a very informal and sporadic manner." More broadly, the report notes that "no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients."

5. Endo.

352. Endo manufactures, and then markets, sells, and distributes the following Schedule II prescription opioids nationwide, including in Plaintiffs' communities:

- **Opana** (oxymorphone hydrochloride). An opioid agonist approved by the FDA in 2006. An extended release version, **Opana ER**, was also approved in 2006.
- **Percodan** (oxycodone hydrochloride and asprin). Endo's branded oxycodone tablet. Approved by the FDA in 1950, first marketed in 2004.
- **Percocet** (oxycodone and acetaminophen). Another branded oxycodone tablet. First approved by the FDA in 1999, first marketed in 2006.
- **Oxycodone, Oxymorphone, Hydromorphone, Hydrocodone**. Endo manufactures and sells generic versions of these prescription opioids.

353. 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."

354. However, oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.[113]

[113] John Fauber & Kristina Fiore, *Opana Gets FDA Approval Despite History of Abuse, Limited Effectiveness in Trials*, Milwaukee Journal Sentinel (May 9, 2015), http://archive.jsonline.com/watchdog/watchdogreports/opana-gets-fda-approval-despite-history-of-abuse-limited-effectiveness-in-trials-b99494132z1-303198321.html/

355. 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."

356. 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 it was crush-resistant.

357. According to Endo's annual reports, sales of Opana and Opana ER regularly generate several hundred million dollars in annual revenue for the company.

a. Endo falsely marketed Opana ER as crush-resistant.

358. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo claimed offered "safety advantages" over the original formulation because the latter "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."

359. 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 formulation.

360. 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."[114]

361. 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."

362. 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 posited that it was not possible to draw a causal link between the reformulation and injection abuse.

363. The study's—and Endo's—failure to adequately warn healthcare providers and the public produced catastrophic results. On April 24, 2015, the CDC issued a health advisory concerning "a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs."[115] The CDC specifically attributed the outbreak to the injection of

[114] Jake Harper & Kelly McEvers, *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, National Public Radio (Apr. 1, 2016), http://www.npr.org/sections/ health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak

[115] Centers for Disease Control and Prevention, Outbreak of Recent HIV and HCV Infections

Opana ER, explaining that "[a]mong 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 finds that Endo falsely marketed Opana ER.

364. 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."

365. 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, concluding that (1) Endo marketed Opana ER as crush-resistant despite its own 2009 and 2010 studies demonstrating this to be untrue; (2) Endo improperly instructed sales reps to diminish and distort the risks associated with Opana ER, including the risk of addiction; and (3) Endo made unsupported claims comparing Opana ER to other opioids.

366. In one instance, in October 2011, Endo's director of project management e-mailed the company that had developed the formulation technology for reformulated 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.[116]

Among Persons Who Inject Drugs, (last visited Mar. 2, 2008), https://emergency.cdc.gov/han/han00377.asp.

[116] *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

367. 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.

368. 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."*[117] 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.

369. 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."[118]

370. 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. 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 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.

(Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

[117] *Id.*

[118] *Id.*

371. 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.

372. 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 not only defied common sense, but was completely inconsistent with the diagnosis of opioid-use disorder as provided in the Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association.

373. The Office of the Attorney General of New York also found that Endo trained its sales representatives to falsely distinguish addiction from the phony malady "pseudoaddiction," discussed elsewhere in this complaint. However, Endo's vice president for pharmacovigilance and risk management testified that he was not aware of any research validating the concept of pseudoaddiction.

374. On June 9, 2017, the FDA asked Endo to voluntarily cease sales of Opana ER after determining that the risks associated with its abuse outweighed the benefits. 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." If Endo does not comply with the request, Dr. Woodcock stated that the FDA would issue notice of a hearing and commence proceedings to compel its removal.

c. Endo funded false publications and presentations.

375. Like the other Manufacturer Defendants, Endo provided substantial funding to purportedly neutral medical organizations, including the APF, to produce false and misleading materials concerning the risks and benefits of prescription opioids.

376. 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*.[119] The article stated that:

> 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.

377. The article included a case study that focused on the danger of extended use of nonsteroidal anti-inflammatory drugs (NSAIDs) (a class of pain relief drugs that includes ibuprofen, among others). The case study reported 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."*

378. Later, in 2014, Endo issued a patient brochure titled "Understanding Your Pain: Taking Oral Opioid Analgesics."[120] It was written by nurses Margo McCaffery and Chris Pasero,

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[119] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain, Pain Med. News*, http://www.painmedicinenews.com/download/ BtoB_Opana_WM.pdf.

[120] Margo McCaffery & Chris Pasero, Understanding Your Pain: Taking Oral Opioid Analgesics, Endo Pharmaceuticals (2004),

and edited by KOL Dr. Portenoy. 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….
>
> 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.

379. 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." 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."

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

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http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

treatment, and management approaches."[121] Among 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.

381. Along with Janssen and Purdue, Endo also provided grants to the American Pain Foundation to distribute *Exit Wounds*, discussed above.

382. Endo also made thousands of payments to physicians nationwide, including to physicians in Plaintiffs' communities, for activities including participating on speakers' bureaus, providing consulting services, and other services.

383. Endo's conduct has clearly been successful. According to data collected by ProPublica, Illinois doctors prescribed over $2 million of Opana ER and over $250,000 of Percocet in 2015 through the Medicare Part D program, and, upon information and belief, millions of dollars' worth of these drugs through private insurance. Upon information and belief, doctors in Plaintiffs' communities have prescribed hundreds of thousands of dollars' worth of Endo's opioid products since their release.

6. Mallinckrodt.

384. Mallinckrodt manufactures, and then markets, sells and distributes pharmaceutical drugs nationwide, including in Plaintiffs' communities. It is the largest U.S. supplier of prescription opioids and among the ten largest generic pharmaceutical manufacturers in the United States. It produces the following Schedule II narcotics:

- **Exalgo** (hydromorphone hydrochloride). An extended release opioid agonist for opioid-tolerant patients, indicated for managing severe pain. Approved by the FDA in March 2010, except for the largest available tablet—32 mg—which was

[121] PainKnowledge, *AboutPainKnowledge.org* (last visited Mar. 2, 2018), http://web.archive.org/web/20130513010647/http://www.painknowledge.org/aboutpaink.aspx.

approved in August 2012.

- **Roxicodone** (oxycodone hydrochloride and acetaminophen). Extended release pill indicated for managing severe, acute pain. Approved by the FDA in March 2014.
- **Methadose** (methadone hydrochloride). Branded generic form of methadone, an opioid agonist, and indicated for treatment of opioid addiction.

Mallinckrodt also produces generic forms of morphine sulfate extended release, fentanyl extended release, fentanyl citrate, oxycodone/acetaminophen combinations, hydrocodone bitartrate/acetaminophen combinations, hydromorphone hydrochloride, hydromorphone hydrochloride extended release, naltrexone hydrochloride, oxymorphone hydrochloride, methadone hydrochloride, and oxycodone hydrochloride.

385. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.[122]

386. Like many of the other Manufacturer Defendants, Mallinckrodt provided substantial funding to purportedly neutral organizations that disseminated false messaging about opioids. For example, until at least May 2012, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as "a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[123]

387. Among other content, the website included a handout titled "Oxycodone Safety Handout for Patients," which advised practitioners that: "Patients' fears of opioid addiction should be dispelled." The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids, such as: "physical dependence … is not the same as addiction … Addiction to oxycodone in persons without a recent history of

[122] Press Release, Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone, Medtronic (Aug. 23, 2012), http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004158.

[123] Pain-Topics.org (last visited May 21, 2018), https://web.archive.org/web/20120502042343/http://pain-topics.org.

alcohol or drug problems is rare."[124]

388. Additionally, the FAQ section of Pain-Topics.org contained false and misleading information downplaying the dangers of prescription opioid use. The FAQ highlighted the risks of "pseudoaddiction," discussed elsewhere in this Complaint, and "pseudo opioid resistance."

389. Another document available on the website, "Commonsense Oxycodone Prescribing & Safety," falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: "Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[125]

390. Mallinckrodt also made thousands of payments to physicians nationwide, including to physicians in Plaintiffs' communities for consulting, speakers' bureau participation, other services.

391. These efforts have proven successful for Mallinckrodt. According to data from ProPublica, Illinois doctors prescribed over $11,057 of Exalgo in 2015 through the Medicare Part D program alone, and tens of thousands of dollars' worth more through private insurance. Upon information and belief**,** doctors in Plaintiffs' communities have prescribed hundreds of thousands of dollars' worth of Mallinckrodt's opioid products since their release.

7. Actavis.

392. Actavis sells Kadian, a Schedule II prescription opioid nationwide, including in Plaintiffs' communities.

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[124] Lee A. Kral & Stewart B. Leavitt, Oxycodone Safety Handout for Patients, Pain-Topics.Org (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

[125] Lee A. Kral, Commonsense Oxycodone Prescribing & Safety, Pain-Topics.org (June 2007), http://paincommunity.org/blog/wp-content/uploads/ OxycodoneRxSafety.pdf.

393. Actavis promoted its branded opioid Kadian through a highly deceptive marketing campaign carried out, principally, through its sales force and recruited physician speakers. The campaign rested on a series of misrepresentations and omissions about the risks, benefits, and superiority of opioids, incorporating many of the same types of deceptive messages otherwise described herein.

394. To help devise its marketing strategy for Kadian, Actavis commissioned a report from one of its consultants in January 2005 about barriers to market entry. The report concluded that two major challenges facing opioid manufacturers in 2005 were (i) overcoming "concerns regarding the safety and tolerability" of opioids, and (ii) the fact that "physicians have been trained to evaluate the supporting data before changing their respective practice behavior."

395. To overcome these challenges, the report advocated a "[p]ublication strategy based on placing in the literature key data that influence members of the target audience" with an "emphasis … on ensuring that the message is believable and relevant to the needs of the target audience." This would entail the creation of "effective copy points … backed by published references" and "developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect profile."

396. According to the report, this would allow physicians to "reach[] a mental agreement" and change their "practice behavior" without having first evaluated supporting data—of which Actavis (and other Defendants) had none.

397. The consulting firm predicted that this manufactured body of literature "w[ould], in turn, provide greater support for the promotional message and add credibility to the brand's advocates" based on "either actual or perceived 'scientific exchange'" in relevant medical literature."

398. To this end, it planned for three manuscripts to be written during the first quarter of 2005. Of these, "[t]he neuropathic pain manuscript will provide evidence demonstrating KADIAN is as effective in patients with presumptive neuropathic pain as it is in those with other pain types;" "[t]he elderly subanalysis … will provide clinicians with evidence that KADIAN is efficacious and well tolerated in appropriately selected elderly patients" and will "be targeted to readers in the geriatrics specialty;" and "[t]he QDF/BID manuscript will …. call attention to the fact that KADIAN is the only sustained-release opioid to be labeled for [once or twice daily] use."

399. In short, Actavis knew exactly what each study would show—and how that study would fit into its marketing plan—before it was published.

400. Articles matching Actavis's descriptions later appeared in the *Journal of Pain* and the *Journal of the American Geriatrics Society* (AGS being one of the many Front Groups discussed above).

401. To ensure that messages based on this science reached individual physicians, Actavis deployed sales representatives, or detailers, to visit prescribers across Cook County and across the country. At the peak of Actavis's promotional efforts in 2011, the company spent $6.7 million on detailing.

402. To track its detailers' progress, Actavis's sales and marketing department actively monitored the prescribing behavior of physicians. It tracked the Kadian prescribing activity of individual physicians, and assessed the success of its marketing efforts by tabulating how many Kadian prescriptions a prescriber wrote after he or she had been detailed.

403. Actavis also planned to promote Kadian by presenting at conferences of organizations where it believed it could reach a high concentration of pain specialists. Its choice

of conferences also was influenced by the host's past support of opioids. For example, Actavis documents show that Actavis presented papers concerning Kadian at an annual meeting of the Front Group AGS because AGS's guidelines "support the use of opioids."

404. Actavis's strategy and pattern of deceptive marketing is evident by looking at its training materials. A sales education module titled "Kadian Learning System" trained Actavis's sales representatives on the marketing messages—including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in Plaintiffs' communities.

405. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, as described above, available data demonstrate that patients on chronic opioid therapy are less likely to participate in daily activities like work.

406. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids. First, Actavis taught its sales representatives, who would pass this message on to doctors, that pain patients would not develop tolerance to opioids, which would require them to receive increasing doses: "Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [chronic pain]." Second, Actavis instructed its sales personnel that opioid "[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose." Actavis failed to explain

to sales representatives (or doctors) the greater risks associated with opioids at high doses.

407. Further, the 2010 sales training module highlighted the risks of alternate pain medications without providing a comparable discussion of the risks of opioids, painting the erroneous and misleading impression that opioids are safer. Specifically, the document claimed that "NSAIDs prolong the bleeding time by inhibiting blood platelets, which can contribute to bleeding complications" and "can have toxic effects on the kidney." Accordingly, Actavis coached its sales representatives that "[t]he potential toxicity of NSAIDs limits their dose and, to some extent, the duration of therapy" since "[t]hey should only be taken short term." By contrast, the corresponding section related to opioids neglects to include a single side effect or risk associated with the use of opioids, including from long-term use.

408. This sales training module also severely downplayed the main risk associated with Kadian and other opioids—addiction. Actavis represented that *"there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction" and, instead, "[i]t appears likely that most substance-abusing patients in pain management practices had an abuse problem before entering the practice."* This falsely suggested that few patients will become addicted, that only those with a prior history of abuse are at risk of opioid addiction, and that doctors can screen for those patients and safely prescribe to others.

409. Further, the sales training neglected to disclose that no risk-screening tools related to opioids have ever been scientifically validated.

410. Finally, the sales training module also directed representatives to counsel doctors to be on the lookout for the signs of "[p]seudoaddiction," which were defined as "[b]ehaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain." However, as described elsewhere, the concept of "pseudoaddiction" is unsubstantiated and meant

to mislead doctors and patients about the risks and signs of addiction.

411. The Kadian Learning System module dates from July 2010, but Actavis sales representatives were passing deceptive messages on to prescribers even before then.

412. A July 2010 "Dear Doctor" letter issued by the FDA indicated that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed … promotional materials that … omitted and minimized serious risks associated with [Kadian]." Certain risks that were misrepresented included the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion." The FDA also took issue with an advertisement for misrepresenting Kadian's ability to help patients "live with less pain and get adequate rest with less medication," when the supporting study did not represent "substantial evidence or substantial clinical experience."

413. Actavis documents also indicate that the company continued to deceptively market its drugs after 2010. For example, a September 2012 Kadian Marketing Update, and the "HCP Detail" aid contained therein, noted that Kadian's "steady state plasma levels" ensured that Kadian "produced higher trough concentrations and a smaller degree of peak-to-trough fluctuations" than other opioids, implying that the drug would produce less of a euphoric effect—and be less addictive and prone to abuse—than other pain relief.

414. Actavis also relied on speakers—physicians whom Actavis recruited to market opioids to their peers—to convey similar marketing messages. Actavis set a goal to train 100 new Kadian speakers in 2008 alone, with a plan to set up "power lunch teleconferences" connecting speakers to up to 500 participating sites nationwide. Actavis sales representatives, who were required to make a certain number of sales visits each day and week, saw the

definition of sales call expanded to accommodate these changes; such calls now included physicians' "breakfast & lunch meetings with Kadian advocate/speaker."

415. A training program for Actavis speakers included training on many of the same messages found in the Kadian Learning System, as described above. The deceptive messages in Actavis's speakers' training are concerning for two reasons: (a) the doctors who participated in the training were themselves prescribing doctors, and the training was meant to increase their prescriptions of Kadian; and (b) these doctors were trained, paid, and directed to deliver these messages to other doctors who would write prescriptions of Kadian.

416. Consistent with the training for sales representatives, Actavis's speakers' training falsely minimized the risk of addiction posed by long-term opioid use. Actavis claimed, without scientific foundation, that "[o]pioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction." The training also deceptively touted the effectiveness of "Risk Tools," such as the Opioid Risk Tool, in determining the "risk for developing aberrant behaviors" in patients being considered for chronic opioid therapy.

417. In recommending the use of these screening tools, the speakers' training neglected to disclose that *none* of them has been scientifically validated.

418. The speakers' training also made reference to "pseudoaddiction" as a "[c]ondition characterized by behaviors, such as drug hoarding, that outwardly mimic addiction but are in fact driven by a desire for pain relief and usually signal undertreated pain." It then purported to assist doctors in identifying those behaviors that actually indicated a risk of addiction from those that did not. Behaviors it identified as "[m]ore suggestive of addiction" included "[p]rescription forgery," "[i]njecting oral formulations," and "[m]ultiple dose escalations or other nonadherence with therapy despite warnings." Identified as "[l]ess suggestive of addiction" were "[a]ggressive

complaining about the need for more drugs," "[r]equesting specific drugs," "[d]rug hoarding during periods of reduced symptoms," and "[u]napproved use of the drug to treat another symptom." By portraying the risks in this manner, the speakers' training presentation deceptively gave doctors a false sense of security regarding the types of patients who can become addicted to opioids and the types of behaviors these patients exhibit.

419. The speakers' training downplayed the risks of opioids, while focusing on the risks of competing analgesics like NSAIDs. For example, it asserted that "Acetaminophen toxicity is a major health concern." The slide further warned that "[a]cetaminophen poisoning is the most common cause of acute liver failure in an evaluation of 662 US Subjects with acute liver failure between 1998-2003," and was titled "Opioids can be a safer option than other analgesics." However, in presenting the risks associated with opioids, the speakers' training focused on nausea, constipation, and sleepiness, and ignored the serious risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness; increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazapines. As a result, the training exaggerated the risks of NSAIDs, both absolutely and relative to opioids, to make opioids appear to be a more attractive first-line treatment for chronic pain.

420. The speakers' training also misrepresented risks associated with increased doses of opioids. For example, speakers were instructed to "[s]tart low and titrate until patient reports adequate analgesia" and to "[s]et dose levels on [the] basis of patient need, not on predetermined maximal dose." However, the speakers' training neglected to warn speakers (and speakers bureau attendees) that patients on high opioid doses are more likely to suffer adverse events.

421. Actavis also continued making thousands of payments to physicians nationwide,

including to doctors in Plaintiffs' communities, for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

422. Meanwhile, Illinois doctors prescribed upon information and belief, thousands of dollars' worth of Kadian through private insurance. Upon information and belief, doctors in Plaintiffs' communities have prescribed thousands of dollars' worth of Kadian since its release.

III. Distributor Defendants Fueled the Opioid Epidemic by Willfully Failing to Perform Basic Diligence In The Wholesale Distribution Of Prescription Opioids.

423. While the supply chain for prescription opioids starts with manufacturers and ends with institutional actors like pharmacies and hospitals, this product stream typically passes through distributors such as Defendants Cardinal, AmerisourceBergen, and McKesson.

424. Together, these three companies account for approximately 85% of all revenues from drug distribution in the United States.

425. Distributor Defendants understand the duties attendant to this role well. Distributor Defendants are members of the Healthcare Distribution Management Association ("HDMA"). The HDMA created industry compliance guidelines which stress the vital role of each supply chain participant in distributing controlled substances such as prescription opioids. HDMA's guidelines, titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," state that "[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process and note in particular that if an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or the distributor otherwise characterizes it as an order of interest, the distributor should not ship the order to the customer.

426. A key reason for performing due diligence is to prevent the "diversion" of prescription opioids. Such diversion occurs whenever the supply chain of prescription opioids allows for such pills to be redirected for an illicit use, including both patently illegal uses (*i.e.*, drug dealing) as well as misuses that, while not necessarily illegal, do not represent the proper use of prescription opioids.

427. All opioid distributors, including Distributor Defendants (and Manufacturer Defendants, as well) are required to maintain effective controls to prevent diversion, including by maintaining a system for identifying and reporting suspicious orders of controlled substances to law enforcement. This is because such products have, as discussed above, carry a high risk of abuse.

428. One aspect of this system is known as the Automation of Reports and Consolidation Orders System ("ARCOS"), an automated reporting system managed by the DEA that oversees the distribution of controlled substances through the supply chain. ARCOS regularly accumulates data on distributors' controlled substance-related transactions and summarizes it into reports that the DEA can use to identify potential cases of diversion.

429. Under federal law, any entity registered to distribute a controlled substance monitored via ARCOS must report acquisition and distribution transactions through it to the DEA. *See* 21 U.S.C. § 827(d)(1); 21 C.F.R. §§ 1304.33(d)–(e). Registrants are also required to maintain complete and accurate records of all controlled substances manufactured, imported, sold, received, delivered, exported, or otherwise disposed of. *See* 21 U.S.C. §§ 827(a)(3), 1304.21(a), 1304.22(b). It is unlawful to fail to abide by these recordkeeping and reporting requirements.

430. In addition, distributors are required to halt shipment of any order of controlled

substances flagged as suspicious, and only ship orders flagged as suspicious if the distributor can determine that the order is not likely to be diverted into illegal channels, following due diligence. *See* Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharm., Inc. v. Drug Enforcement Admin*., No. 15-11355 (D.C. Cir. June 30 2017).

431. Finally, pursuant to DEA regulations, distributors are required to maintain effective controls to prevent opioid diversion in the supply chain, so that controlled substances are not funneled into anything other than legitimate channels. The DEA assesses the efficacy of a distributor's controls pursuant to the requirements of 21 C.F.R. §§ 1301.72–76, including the aforementioned requirement that all registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b).

432. The State of Illinois incorporates all of these federal requirements into state law. *See* Ill. Admin. Code § 1510.50(i) ("Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.") It also broadly prohibits wholesale drug distributors from "[e]ngaging in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public." 225 ILCS 120/55(a)(4).

433. Opioid diversion has increased significantly in the United States over the last two decades, and occurs at a disturbingly high rate.[126] Sales of prescriptions opioids nearly quadrupled from 1999 to 2014, and by 2010 enough opioids were sold in the United States to give every adult in the country a five milligram dose of hydrocodone every four hours for a month.[127] Because there is a "parallel relationship between the availability of prescription

[126] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconception and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016); Richard C. Dart, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).
[127] Centers for Disease Control and Prevention, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999–2008* (November 4, 2011),

opioid[s] … and the diversion and abuse of these drugs," it should be unsurprising that as the amount of opioid prescriptions has increased, there have been "millions of controlled substance dosage units" diverted.[128]

434. In 2011, the Centers for Disease Control and prevention publicly stated that prescription painkiller overdoses had reached epidemic levels, in light of the tripling of painkiller overdoses over the previous decade, the fact that painkillers kill more Americans annually than heroin and cocaine combined, and that almost 5,500 people begin misusing prescription painkillers *daily*.[129]

435. Today, the number of people who take prescription opioids for non-medical purposes outnumbers those who take cocaine, heroin, hallucinogens, and inhalants combined.

436. This increase has been widely publicized for years, with scientific studies, federal and state agencies, professional organizations, and media outlets highlighting the epidemic levels of prescription opioid abuse throughout the United States. Put simply, the opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications" largely made available through diversion.[130]

437. Thus, each Distributor Defendant has admitted that they have a responsibility to report suspicious orders through the procedures outlined above, and for the reasons outlined

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https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w%20-%20fig2.

[128] Richard C. Dart, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015);

[129] See Press Release, Ctrs. For Disease Control and Prevention, *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html

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

above.[131] But at various over the past two decades, each of these three distributors has utterly failed to do so. This is despite acknowledging that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[132]

438. Thus, Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders of opioids. However, they sold prescription opioids—including various forms of Manufacturer Defendants oxycodone, hydrocodone, and fentanyl—to retailers in Plaintiffs' communities and/or retailers which Distributor Defendants knew (or should have known) would likely divert prescription opioids into Plaintiffs' communities. The foreseeable harm resulting from the breach of these duties was widespread diversion of prescription opioids for unapproved purposes, and a subsequent plague of opioid abuse, addiction, overdose, and death in Plaintiffs' communities—and the attendant damages caused thereby.

439. Distributor Defendants negligently or intentionally failed to controlled their supply chain to prevent diversion in Plaintiffs' communities. Reasonably prudent distributors of Schedule II controlled substances would have anticipated such dangers and protected against it

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[131] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin*. No. 15-1335, 2016 WL 1321983, at *4 (D.C. Cir. Apr. 4, 2016) ("[R]egulations … in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (*e.g.,* a pharmacy's placement of unusually frequent or large orders). The Healthcare Distribution Management Association (HDMA or HMA)— now known as the Healthcare Distribution Alliance (HAD)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HAD, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017).

[132] *Prescription Drug Diversion: Combating the Scourge*, Before the *H. Subcomm. on Commerce, Manuf'g, and Trade*, 112th Congr. 105 (2012) (Statement of John M. Gray, President and Chief Executive Office, Healthcare Distribution Management Association (HDMA)).

by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; scrutinizing more closely the doctors and pharmacies purchasing suspiciously-large quantities of commonly-abused opioids from them; investigating the demographic and/or epidemiological facts surrounding the growing demand for painkillers in and around Plaintiffs' communities; providing information to pharmacies and other retailers about opioid diversion; following the terms of agreements with the U.S. Department of Justice; and, finally, applying a level of common sense commensurate with their role as opioid distributors.

440. Distributor Defendants did none of these things, or did them with such lack of care and inefficacy as to allow for widespread diversion of opioids to unapproved and illegal uses. Examples of each Distributor Defendant's conduct follows.

A. McKesson Corporation.

441. McKesson is a wholesale pharmaceutical distributor and one of the largest opioid distributors in the country, supplying pharmacies around the country—including in Plaintiffs' communities—with prescription opioids like oxycodone and hydrocodone. It is also a major supplier of fentanyl, accounting nationwide for about 17 percent of all sales of Subsys, a fentanyl product manufactured by Defendant Insys.

442. McKesson operates 28 pharmaceutical distribution centers, including a distribution center in Aurora, Illinois, and elsewhere around the United States.[133]

443. The company holds a third of the market for prescription drugs in the U.S.[134] Based on an average 2010–16 opioid prescription rate in Plaintiffs' surrounding counties (Cook

[133] Erika Fry, *Following the Pills: Inside the Government's Investigation of McKesson*, Fortune (June 13, 2017), http://fortune.com/2017/06/13/mckesson-drug-distributors-opioid-epidemic/.
[134] Adam J. Fein, *2016 MDM Market Leaders | Top Pharmaceutical Distributors*, MDM (last visited Mar. 6, 2018), https://www.mdm.com/2016-top-pharmaceuticals-distributors.

and Peoria) of 72.15 opioid prescriptions for every 100 people, McKesson has—on information and belief—supplied tens of thousands of people in Plaintiffs' communities with opioids each year.[135]

444. McKesson distribution centers are required by Illinois law to operate in accordance with the statutory provisions of the Controlled Substances Act and the regulations promulgated thereunder. Ill. Admin. Code § 1510.50(i).

445. McKesson is an astoundingly successful company, with revenues of nearly $200 billion in 2016 *alone*.[136] McKesson's opioid business—including sales of products containing oxycodone and hydrocodone—has been an important part of this success, accounting for $2.9 billion in revenue for the company in 2015.[137] Another estimate places its annual sales revenue from opioids at approximately $4 billion per year, on average.[138]

446. However, McKesson's success in distributing opioids over the past decade has been marked by multiple run-ins with law enforcement over its shoddy monitoring and reporting practices. As detailed herein, McKesson has repeatedly failed to implement reasonable, basic safeguards to prevent its products from falling into the wrong hands; misrepresented the safeguards it was implementing; and deliberately misled the public, in Plaintiffs' communities and elsewhere, about measures it was taking to ensure its addictive products were not subjected to diversion.

447. In December 2016, responding to an article in the *Washington Post* about the

[135] *See generally* Centers for Disease Control and Prevention, *U.S. Prescription Rate Maps* (last visited Apr. 5, 2018), https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.
[136] S.E.C. Form 10-K, McKesson Corporation (May 22 2017), *available at* http://bit.ly/2ESsjco/.
[137] Erika Fry, *Following the Pills: Inside the Government's Investigation of McKesson*, Fortune (June 13, 2017), http://fortune.com/2017/06/13/mckesson-drug-distributors-opioid-epidemic/.
[138] Brian Alexander, *When A Company Is Making Money From the Opioid Crisis*, The Atlantic (Sept. 6, 2017), https://www.theatlantic.com/business/archive/2017/09/opioid-crisis-responsibility-profits/538938/.

company's practice of hiring former DEA employees, McKesson said in a statement that it "has put significant resources towards building a best-in-class controlled substance monitoring program to help identify suspicious orders and prevent prescription drug diversion in the supply chain."[139]

448. Were this true, it would have represented a complete shift in McKesson's previously careless approach, which as recently as 2017 had drawn the attention of law enforcement authorities.

449. In 2006 and 2007, the DEA sent letters to every registered manufacturer or distributor of controlled substances, including the Defendants, in part reiterating the distributors' monitoring and reporting obligations under the Controlled Substances Act.[140] In the 2007 letter, the DEA reminded registrants that "their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."

450. In addition, the DEA clarified that the "suspicious orders include orders of an

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[139] Scott Higham, et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.271f2be40525.

[140] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, dkt. 14-51 (D.D.C. Feb. 10, 2012); *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, dkt. 14-8 (D.D.C. Feb. 10, 2012).

unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive … Likewise, a registrant need not wait for a 'normal pattern' to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious."

451. In 2007, the DEA accused McKesson of failing to report numerous suspicious orders for its opioid products (particularly from internet-based pharmacies) and began an investigation into its practices, with the DEA's acting administrator later stating that "McKesson Corporation fueled the explosive prescription drug abuse problem we have in this country."[141]

452. On May 2, 2008, McKesson agreed to pay the U.S. government $13.25 million to settle the case, and agreed to improve its opioid distribution monitoring by—in part—implementing a three-tiered system that would flag buyers who exceeded monthly thresholds for opioids. According to an article in *Fortune*, the process was supposed to function as follows:

> Under this three-tier system, each of McKesson's pharmacy customers were assigned monthly threshold levels for their controlled substance orders. Orders at the threshold would block the order and trigger a review process. If the reason for reaching the threshold level was compelling, McKesson would supply the drugs and in some cases raise the threshold; if not, the matter would be passed to a regional compliance officer. If that officer deemed it suspicious, the order would be kicked up to McKesson's corporate compliance team. If they also judged it suspicious, the company would then report the order to the DEA.[142]

453. While McKesson was supposed to develop this Controlled Substances Monitoring Program pursuant to its agreement with the Department of Justice, it failed to design or

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[141] Erika Fry, *As America's Opioid Crisis Spirals, Giant Drug Distributor McKesson is Feeling the Pain*, Fortune (June 13, 2017), http://fortune.com/2017/06/13/fortune-500-mckesson-opioid-epidemic/.

[142] *Id.*

implement an effective system for identifying and reporting suspicious orders for opioids. It additionally failed to conduct basic due diligence of its customers, failed to keep complete and accurate records attendant to the monitoring program, and failed to actually adhere to the procedures it created for itself.

454. According to documents filed in a recent shareholder lawsuit against McKesson, just five months after the 2008 settlement was announced the audit committee of the McKesson Board of Directors was notified that there were "serious deficiencies" in its monitoring system, including a failure to assign opioid thresholds for some customers (which would trigger a review of the purchases, in theory) and a lack of documentary evidence to support imposing thresholds on others.

455. Rather than address the problems head on, records show that McKesson's board of directors did not even discuss its compliance system until 2013. In the interim five years, inspections of some of McKesson's distribution facilities had revealed a failure to "fully implement or adhere to its own" compliance program. Indeed, from 2008 onwards McKesson regularly honored pharmacies' request for large opioid shipments based on the flimsiest of rationales, such as "more business" during the holiday season or "increase in foot traffic."[143]

456. In 2013, the DEA began investigating McKesson again, in response to reports it was failing to prevent opioid diversion and follow its own system for identifying and reporting suspicious orders of opioids from pharmacies, as the Controlled Substances Act—as well as its 2008 settlement—required.

457. This investigation led to the January 17, 2017 announcement that the Department of Justice was fining McKesson $150 million as part of a settlement over claims McKesson had

[143] *Id.*

allowed opioid diversion at twelve of its distribution centers in eleven states. This represented one of the largest such sanctions imposed on a pharmaceutical distributor.

458. McKesson was also forced to suspend sales of controlled substances from four of its distribution centers. It also, for the first time ever in the context of a Controlled Substances Act settlement, was required engage an independent monitor to assess its compliance with a new, enhanced compliance regime, going forward.

459. The Department of Justice stated that McKesson had not, as documented above, adequately reported suspicious orders of opioids from 2008 to 2013, nor implement the monitoring and reporting programs it had agreed to in 2008.[144] For instance, of 1.6 million orders for controlled substances McKesson received at a Colorado distribution facility over a five-year period, the company reported just 16 orders as suspicious—all derived from a single instance with one customer.[145] This instance took place in March 2012, according to a news report in the year following the settlement, four years after McKesson had agreed to implement its Controlled Substance Monitoring Program, and despite the presence of numerous red flags in other orders (such as one pharmacy's increasing its orders of 30mg oxycodone pills by 1,469 percent in just three years).[146]

460. Upon information and belief, at least part of the reason McKesson's Controlled Substance Monitoring Program failed to adequately flag suspicious orders during this period was

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[144] Dep't of Justice, *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[145] Gretchen Morgenson, *Hard Questions for a Company at the Center of the Opioid Crisis*, N.Y. Times (July 21, 2017), https://www.nytimes.com/2017/07/21/business/mckesson-opioid-packaging.html?mtrref=www.google.com.

[146] Erika Fry, *Following the Pills: Inside the Government's Investigation of McKesson*, Fortune (June 13, 2017), http://fortune.com/2017/06/13/mckesson-drug-distributors-opioid-epidemic/.

McKesson's decision to set customer "thresholds" for opioid orders at inappropriately high levels (assuring a review would never be triggered) or to preemptively raise those thresholds. In other cases, upon information and belief, McKesson simply ignored the thresholds it set altogether.

461. Pursuant to its agreement with the Department of Justice, McKesson acknowledged that "at various times … it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008" agreement and McKesson's own Controlled Substances Monitoring Program. It also admitted that "at various times during the period from January 1, 2009 up through and including [the effective date of the settlement], it did not identify or report to the DEA certain orders which should have been detected by McKesson as suspicious based on" letters it had received from the DEA in 2006 and 2007.[147]

462. Finally, McKesson admitted that its distribution centers "distributed controlled substances to pharmacies even though those [distribution centers] should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes," as is required by 21 C.F.R. § 1306.04(a).

463. These failures, the memorandum stated, applied to McKesson's conduct at its distribution center in Aurora, Illinois.

464. McKesson's internal regulatory failures, as described above, would have been obvious to any reasonable observer, both at the executive level and at ground level, looking at the company's national sales practices and the widespread diversion of prescription opioids

[147] Dep't of Justice, Administrative Memorandum of Agreement, at 3 (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.

taking place during this period.[148] Nonetheless, McKesson's pattern of carelessness continued unabated on for a decade before the Department of Justice stepped in.

B. AmerisourceBergen.

465. AmerisourceBergen is a wholesale distributor of pharmaceuticals, handling about 20 percent of all pharmaceuticals sold and distributed in the United States through a network of 26 distribution centers, including one in Romeoville, Illinois. In 2017, the company ranked 11th on the Fortune 500 list, with over $146 billion in annual revenue.

466. The company holds a 30 percent share of the market for prescription drugs in the U.S.[149] Based on an average 2010–16 opioid prescription rate in Plaintiffs' surrounding counties (Cook and Peoria) of 72.15 opioid prescriptions for every 100 people, AmerisourceBergen has—on information and belief—supplied tens of thousands of residents of Plaintiffs' communities with opioids each year.[150]

467. AmerisourceBergen distribution centers are required under Illinois law to operate in accordance with the statutory provisions of the Controlled Substances Act and the regulations promulgated thereunder. Ill. Admin. Code § 1510.50(i).

468. In April 2007, the DEA suspended AmerisourceBergen from sending controlled substances from a distribution center in Orlando, Florida amid allegations it was not controlling shipments of prescription opioids to Internet pharmacies.[151] Indeed, in one year, the company

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[148] For example, in a single year McKesson shipped 3.3 million hydrocodone pills into a single West Virginia County with a population of less than 30,000. Eric Eyre, *Drug Firms Poured 780M Painkillers Into WV Amid Rise of Overdoses*, Charleston Gazette-Mail (Dec. 17, 2016), http://bit.ly/2DO0xP3.

[149] Adam J. Fein, *2016 MDM Market Leaders | Top Pharmaceutical Distributors*, MDM (last visited Mar. 6, 2018), https://www.mdm.com/2016-top-pharmaceuticals-distributors.

[150] *See generally* Centers for Disease Control and Prevention, *U.S. Prescription Rate Maps* (last visited Mar. 6, 2018), https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

[151] Reuters Staff, *AmerisourceBergen Gets DEA Distribution Halt Order*, Reuters (Apr. 24,

distributed 3.8 million units of hydrocodone to "rogue pharmacies."[152] As part of an agreement with the DEA to get its license reinstated—which it did, in August 2007—AmerisourceBergen agreed to implement "an enhanced and more sophisticated order monitoring program in all" of its distribution centers.[153] This did not happen.

469. In 2012, AmerisourceBergen was again implicated for failing to protect against diversion, and was subpoenaed as part of a criminal inquiry by the Department of Justice.[154]

470. In January 2017, AmerisourceBergen revealed in litigation with the state of West Virginia based on similar allegations that the company, along with the other Distributor Defendants, shipped over 400 million painkillers into the state between 2007 and 2012.[155] AmerisourceBergen, specifically, added 80.3 million hydrocodone pills and 38.4 million oxycodone pills to this total, with the average dose of each tablet distributed growing substantially during that period. The company settled the claims for $16 million, and agreed to adhere to stricter reporting guidelines within the state.

471. AmerisourceBergen has repeated this conduct in Illinois and in Plaintiffs' communities, shipping mass quantities of oxycodone and hydrocodone into their villages, towns,

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2007), https://www.reuters.com/article/amerisourcebergen-dea/amerisourcebergen-gets-dea-distribution-halt-order-idUSWEN695120070425.

[152] Press Release, Drug Enforcement Admin., DEA Suspends Orlando Branch Of Drug Company From Distributing controlled Substances (Apr. 24, 2007), https://www.dea.gov/divisions/mia/2007/mia042407p.html.

[153] Press Release, AmerisourceBergen, DEA Reinstates AmerisourceBergen's Orlando Distribution Center's Suspended License To Distribute Controlled Substances (Aug. 27, 2007), *available at* http://bit.ly/2oIm6tq.

[154] Jeff Overly, *AmerisourceBergen Subpoenaed By DEA Over Drug Diversion*, Law360.com (Aug. 9, 2012), https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion.

[155] *See e.g.*, Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail (Dec. 17, 2016), http://www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses.

and cities without regard for its reasonably foreseeable consequences and in violation of its obligations under Illinois law.

C. Cardinal Health.

472. Cardinal Health is a healthcare services and products company that distributes prescription opioids in the United States. It ranks 15th on the Fortune 500 list, with revenues of over $121 billion annually.

473. Cardinal Health operates distribution centers across the country, including centers in Aurora and Waukegan, Illinois.

474. The company holds a 22 percent share of the market for prescription drugs in the U.S.[156] Based on an average 2010–16 opioid prescription rate in Plaintiffs' surrounding counties (Cook and Peoria) of 72.15 opioid prescriptions for every 100 people, Cardinal Health has—on information and belief—supplied tens of thousands of people in Plaintiffs' communities with opioids each year.[157]

475. The company has two operating divisions: pharmaceutical and medical. Its pharmaceutical segment, at issue in this action, distributes both branded and generic pharmaceutical products in the United States. The vast majority of the company's revenue stream—upon information and belief, approximately 90 percent—is derived from the pharmaceutical division.

476. Cardinal Health is a significant distributor of prescription opioids in the United States and in Plaintiffs' communities. Its largest customer is CVS Health, which accounted for one-quarter of the company's fiscal year 2016 revenue. According to its website, CVS operates

[156] Adam J. Fein, *2016 MDM Market Leaders | Top Pharmaceutical Distributors*, MDM (last visited Mar. 6, 2018), https://www.mdm.com/2016-top-pharmaceuticals-distributors.

[157] *See generally* Centers for Disease Control and Prevention, *U.S. Prescription Rate Maps* (last visited Mar. 6, 2018), https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

stores in and around Plaintiffs' communities, including (but not limited to) locations in Bridgeview, Cicero, Melrose Park, Pekin, and Tinley Park.

477. Cardinal Health distribution centers are required under Illinois law to operate in accordance with the statutory provisions of the Controlled Substances Act and the regulations promulgated thereunder. Ill. Admin. Code § 1510.50(i). Yet the company has been found to have flouted these requirements.

478. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health's distribution center in Auburn Washington, for failing to maintain effective diversion controls for hydrocodone. The next month, the DEA issued two more Suspension Orders against Cardinal Health's distribution centers in Lakeland, Florida and Swedesboro, New Jersey, again over hydrocodone diversion. The DEA issued one more Suspension Order over hydrocodone diversion controls, in January 2008, against Cardinal Health's distribution center in Stafford, Texas.

479. On September 30, 2008, Cardinal Health entered into a settlement with the DEA over these suspended facilities requiring it to implement effective controls against the diversion of controlled substances. The document referenced allegations about diversion at three additional facilities in McDonough, Georgia; Valencia, California; and Denver, Colorado.

480. Nevertheless, in February 2012 the DEA suspended the license of Cardinal Health's Lakeland, Florida distribution center once again, this time for failing to maintain effective controls to prevent the diversion of oxycodone.

481. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including

oxycodone, to the DEA.[158] (Earlier in 2016, CVS also agreed to pay the United States $8 million to resolve violations of the CSA by its Maryland pharmacies. According to the settlement agreement, CVS admitted that between 2008 and 2012 certain of its Maryland pharmacies dispensed oxycodone, fentanyl, hydrocodone and other pharmaceuticals in violation of the CSA because the drugs were dispensed without ensuring that the prescriptions were issued for legitimate medical purposes.)

482. Pursuant to its settlement agreement with the DEA, Cardinal Health admitted that it had violated the CSA between January 1, 2011 and May 14, 2012 by, among other things, failing to (1) "timely identify suspicious orders of controlled substances and inform the DEA of those orders," (2) "maintain effective controls against diversion of particular controlled substances," and (3) "execute, fill, cancel, correct … and otherwise handle DEA 'Form 222' … and their electronic equivalent for Schedule II controlled substances."[159]

483. Despite this, Cardinal Health has claimed to be a paragon of compliance. For example, a Cardinal Health executive claimed that the company uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[160]

484. Given the company's sales volume in Plaintiffs' communities, in Illinois, and

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[158] Press Release, U.S. Attorney's Office for the District of Maryland, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

[159] Consent Order, *United States v. Kinray, LLC*, Case No. 16 Civ. 9767-RA, Dkt. 3 (Dec. 22, 2016).

[160] Lenny Bernstein, et al., *How Drugs Intended For Patients Ended Up In The Hands Of Illegal Users: 'No One Was Doing Their Job'*, Wash. Post. (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

around the country, and its history of violations, this executive was either ignorant, misinformed, or simply not telling the truth. Cardinal Health has shipped mass quantities of oxycodone and hydrocodone into Plaintiffs' villages, towns, and cities without regard for its reasonably foreseeable consequences and in violation of its obligations under Illinois law.

IV. Prescriber Defendants Operated A "Pill Mill," Illegally Prescribing Enormous Quantities of Opioids to Residents of Plaintiffs' Communities.

485. At the end of the opioid supply chain lies the retail pharmacies that dispense Manufacturer and Distributor Defendants' drugs to consumers.

486. Among these entities is Melrose Park Clinic, Ltd., which has operated under the name Riverside Pain Management since at least January 1, 2013.[161] For purposes of this Section, the following allegations will refer to all relevant entities operated through this corporate entity as "Melrose Park Clinic."

A. Defendant Giacchino.

487. Defendant Giacchino first received his Illinois medical license in 1974.[162] At or around this time, Giacchino obtained a license to dispense controlled substances in Illinois.

488. The Melrose Park Clinic was incorporated in Illinois on June 11, 1985 by Defendant Giacchino.

489. Giacchino's conduct over the next three decades—and particularly his conduct in the 2000s—has fit a distinct pattern, in which Defendant repeatedly flouted professional standards, state regulations, and the law of Illinois in order to dispense vast quantities of opioids to patients throughout Cook County, including, upon information and belief, patients in

[161] Bob Uphues, *Controversial Ex-Doc Rents Space For Medical Office In Riverside*, Riverside-Brookfield Landmark (Jan. 15, 2013), http://www.rblandmark.com/News/Articles/1-11-2013/Controversial-ex_doc-rents-space-for-medical-office-in-Riverside/.

[162] *Giacchino*, 2013 IL App (1st) 122694-U, ¶ 3.

Plaintiffs' communities.

490. In doing so, his conduct has been so brazen and destructive as to earn him the nickname "Dr. Millionpills.'"[163]

491. Two years after founding the Melrose Park Clinic, Giacchino's licenses were suspended by the Illinois Department of Financial and Professional Regulation ("IDFPR") for "dispensing controlled substances for non-therapeutic purposes."[164] In September 1989, the IDFPR restored his physician's license—subject to a five-year probationary period—but maintained, indefinitely, the suspension of his controlled substances license.[165]

492. The IDFPR restored Giacchino's controlled substance license, subject to a two-year probationary period, in June 1998.[166]

493. Giacchino once again began to operate out of the Melrose Park Clinic's locations in Melrose Park, Illinois, and later in River Grove, Illinois. Upon information and belief, soon afterwards Giacchino began reengaging in his illicit prescribing behavior during and throughout this time period, in earnest, prescribing vast quantities of opioids to patients (including those in Plaintiffs' communities) without performing the basic diligence required of his profession, and without regard for those patients' susceptibility to, or then-ongoing, drug addiction.

494. On April 22, 2010, the IDFPR's Director granted an emergency petition to summarily suspend Giacchino's licenses pending a hearing before the IDFPR, finding that Giacchino's conduct constituted an immediate danger to the public. The IDFPR subsequently filed an 18-count administrative complaint against Giacchino alleging violations of Illinois'

[163] John Kass, *The Doctor, The Centerfold Wife and 1 Million Pills*, Chi. Trib. (May 20, 2010), http://articles.chicagotribune.com/2010-05-20/news/ct-met-kass-giacchino-0520-20100520_1_drug-enforcement-administration-agent-narcotics-abusers.
[164] *Giacchino*, 2013 IL App (1st) 122694-U, ¶ 3.
[165] *Id.*
[166] *Id.* ¶ 4.

Medical Practice Act and Controlled Substances Act.

495. Following a hearing on the complaint—in which a DEA Agent named Mark Warpness testified that Giacchino had been purchasing over 1 million pain pills per year—an Administrative Law Judge found, among other things, that Dr. Giacchino had violated Illinois' Medical Practice Act and Controlled Substances Act by, among other things, prescribing opioids to patients in large quantities on a monthly basis without obtaining detailed medical histories, conducting thorough and complete physical examinations, or attempting non-narcotic treatment.[167]

496. The ALJ noted that Giacchino's prescribing "such large amounts of controlled substances at each visit was not for a medically accepted therapeutic purpose."[168] In addition, the ALJ found that Giacchino had engaged in dishonorable, deceptive conduct; engaged in sexual misconduct related to his practice by—effectively—offering a patient pain pills in exchange for sexual relations; made fraudulent statements by post-dating prescriptions for Norco (manufactured by Defendant Actavis); and knowingly providing prescriptions to drug addicts.[169]

497. On April 6, 2011, IDFPR's Medical Disciplinary Board adopted the ALJ's findings of fact and conclusions of law, accepted the ALJ's recommended decision, and recommended the revocation of Giacchino's medical license. On June 15, 2011, the IDFPR Director formally revoked Giacchino's medical licenses, a decision which was ultimately upheld by an Illinois appellate court in 2013.[170]

498. As discussed below, this turn of fortune hardly stopped Giacchino's behavior. It

[167] John Kass, *The Doctor, The Centerfold Wife and 1 Million Pills*, Chi. Trib. (May 20, 2010), http://articles.chicagotribune.com/2010-05-20/news/ct-met-kass-giacchino-0520-20100520_1_drug-enforcement-administration-agent-narcotics-abusers.
[168] *Giacchino*, 2013 IL App (1st) 122694-U, ¶ 63.
[169] *Id.* ¶¶ 65–69.
[170] *Giacchino*, 2013 IL App (1st) 122694-U, ¶¶ 71–74, 116.

merely required a shift in practices in order to continue doing what he had been doing for years: selling vast quantities of opioids to residents of Plaintiffs' communities for his personal enrichment.

B. Defendants McMahon and Madison.

499. Defendant McMahon practiced medicine under Illinois medical and controlled substances licenses until 2016 when his medical license was suspended.

500. Defendant Madison similarly had his medical license suspended in 2016. Previously, Defendant Madison practiced anesthesiology. He has also billed himself as a "pain management specialist."

501. During the relevant time period, Madison worked for three entities relevant to this complaint: Watertower SurgiCenter LLC ("Watertower SurgiCenter") in Chicago, Illinois; Midwest Pain Clinic in Michigan City, Indiana; and, as of 2010, Melrose Park Clinic.

502. Madison was never an oncologist during his medical career—indeed, he has treated few cancer patients in his career. Most of his patients came to him seeking treatment of back and neck pain, or for other types of chronic non-cancer pain.

503. Upon information and belief, Madison's primary method of treating patients for pain, including chronic non-cancer pain, was through the use of prescription opioids.

504. In 2010, Madison took on a new line of work when he was named president of the corporation Melrose Park Clinic, following the suspension of the medical license of its former president, Defendant Giacchino.[171] Madison remained president of Melrose Park Clinic until its involuntary dissolution in 2017.

[171] Bob Uphues, *Controversial Ex-Doc Rents Space For Medical Office In Riverside*, Riverside-Brookfield Landmark (Jan. 11, 2013), http://www.rblandmark.com/News/Articles/1-11-2013/Controversial-ex_doc-rents-space-for-medical-office-in-Riverside/.

505. In December 2012, Madison was indicted on federal False Claims Act charges over his alleged billing of insurers for over $3 million for procedures that were never performed, while practicing in Chicago.[172]

506. In 2015, the state of Michigan suspended Madison's license to practice medicine.[173] And Madison's medical license would ultimately be suspended by the IDFPR on November 29, 2016, in relation to his work for the Melrose Park Clinic—specifically, for prescribing prescription opioids for non-therapeutic purposes.

507. His license remains suspended to this day.[174]

508. In November 2016, Madison was named as an unindicted co-conspirator in a federal lawsuit filed in November 2016 in Massachusetts against Manufacturer Defendant Insys. The lawsuit identified Madison as a KOL used by Insys to help promote its fentanyl oral spray product Subsys. In exchange, Madison received over $87,000 in fees at sham speaking engagements attended almost exclusively by the company's sales representatives, or, occasionally, doctors who did not specialize in treating cancer-related pain.

509. Madison's speeches, according to the complaint, were titled "Advancements in the Treatment of Breakthrough Pain In Cancer Patients," despite his near-total lack of experience

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[172] Lois Tomaszewski, *Michigan City Doctor Indicted On Federal Health Fraud Charges*, Mich. City News-Dispatch (Dec. 26, 2012), http://www.thenewsdispatch.com/news/local/article_29778267-c41c-5d03-a67e-4dbb4346f639.html.

[173] Carla K. Johnson, *Regulators: Illinois Doctor's Pill Mill Supplied 11 States*, Associated Press (Nov. 30, 2016), http://chicago.cbslocal.com/2016/11/30/regulators-illinois-doctors-pill-mill-supplied-11-states/.

[174] Bob Uphues, *Lawyer Wants Out Of Riverside Pain Doc's Case*, Riverside-Brookfield Landmark (Feb. 21, 2017), Bob Uphues, *Controversial Ex-Doc Rents Space For Medical Office In Riverside*, Riverside-Brookfield Landmark (Jan. 11, 2013), http://www.rblandmark.com/News/Articles/1-11-2013/Controversial-ex_doc-rents-space-for-medical-office-in-Riverside/.

treating cancer patients.[175] Madison spoke at approximately 46 such events in the Chicago area between November 2012 and June 2015.

510. Madison, the complaint alleges, was seen as a "go to physician" by the company, who—according to an email from an Insys sales representative—ran "a very shady pill mill and only accepts cash…[and] basically just shows up to sign his name on the prescription pad."

511. Indeed, until 2016 Madison was the top Subsys prescriber in Illinois, dispensing as much as 58 percent of all Subsys prescriptions in the state.[176] Of these prescriptions, the attorney general alleged, more than 95 percent were not for the treatment of breakthrough cancer pain.

512. Similarly, Defendant McMahon also received benefits from Insys in 2015. Upon information and belief, these benefits came in the form of free food and drink at one of the sham "speaking engagements" featuring Defendant Madison.

C. Prescriber Defendants Operated a Pill Mill at the Melrose Park Clinic.

513. Just after January 1, 2013, the doors of Melrose Park Clinic's new location in Riverside, Illinois opened. Working behind the counter was a familiar face: Defendant Giacchino, who told a reporter that he was merely serving as the clinic's administrator, "answering phones, clearing up and processing paperwork."[177]

514. Giacchino also said that Defendant Madison would be the doctor treating patients

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[175] Jessica Huseman, *Illinois Sues Controversial Drug Maker Over Deceptive Marketing Practices*, ProPublica (Aug. 29, 2016), https://www.propublica.org/article/illinois-sues-controversial-drug-maker-over-deceptive-marketing-practices.

[176] Jessica Huseman, *Illinois Sues Controversial Drug Maker Over Deceptive Marketing Practices*, ProPublica (Aug. 29, 2016), https://www.propublica.org/article/illinois-sues-controversial-drug-maker-over-deceptive-marketing-practices.

[177] Bob Uphues, *Controversial Ex-Doc Rents Space For Medical Office In Riverside*, Riverside-Brookfield Landmark (Jan. 11, 2013), http://www.rblandmark.com/News/Articles/1-11-2013/Controversial-ex_doc-rents-space-for-medical-office-in-Riverside/.

at Melrose Park Clinic's new location. Defendant McMahon was also brought on to work at Melrose Park Clinic.

515. Upon information and belief, Melrose Park Clinic was—as it had been at its prior location—merely a pill mill, dispensing opioid prescriptions to virtually all comers, regardless of their claimed ailment, the presence of any number of 'red flags' for potential diversion that any reasonable clinic operator would take notice of, and without performing the most basic medical procedures to determine whether opioids were necessary. The primary qualification a patient needed to receive opioids from Prescriber Defendants was cash.

516. The prescriptions McMahon and Madison issued did not remain in Riverside, but made it as far as 100 miles away.[178] Indeed, the IDFPR ultimately found that Madison's opioid prescriptions were distributed to patients from as many as 11 states, including California, Florida, Iowa, Indiana, Michigan, Minnesota, Ohio, Oklahoma, Tennessee, and Wisconsin.[179]

517. As a consequence of their conduct, Defendants Madison and McMahon had their medical licenses suspended in November 2016 for prescribing opioids for non-therapeutic purposes, including through their work at the Melrose Park Clinic.

518. In the petition to temporarily suspend Defendant McMahon's license, the Chicago office of the DEA sent a confidential informant to Melrose Park Clinic. During those visits, McMahon provided the source with *six* prescriptions for Norco—which contains hydrocodone—in the amount of 90 pills per prescription, without ever examining the patient or performing any tests. The source "walked into the office in July and handed $200 to Giacchino" at the front desk,

[178] Bob Uphues, *Riverside Pain Doc's License Pulled By State*, Riverside-Brookfield Landmark (Nov. 8, 2016), http://www.rblandmark.com/News/Articles/11-8-2016/Riverside-pain-doc's-license-pulled-by-state/.

[179] Carla K. Johnson, *Regulators: Illinois Doctor's Pill Mill Supplied 11 States*, Associated Press (Nov. 30, 2016), http://chicago.cbslocal.com/2016/11/30/regulators-illinois-doctors-pill-mill-supplied-11-states/.

who "put the money into his pocket," after which the source "met with McMahon for about 60 seconds before walking out with the prescriptions." The same thing happened during the source's second visit a month later.[180]

519. According to the ultimately-approved suspension petition, McMahon prescribed hundreds of thousands of units of hydrocodone and oxycodone over the course of two-plus years at Melrose Park Clinic.

520. Defendant Madison, meanwhile, was found to have provided as much as 1.6 *million* doses of controlled substances from 2015 to 2016 to patients in eleven states, including Illinois, and giving patients cursory examinations (or none at all) before dispensing opioids to them.[181] Upon information and belief, a substantial portion of these doses were prescribed through Madison's work for the Melrose Park Clinic.

521. The fact that buyers were willing to drive hundreds of miles to Prescriber Defendants' clinic to procure opioids would have, and should have, been a clear red flag to a reasonable clinic operator that their clinic was being used as a ready source for prescription opioids to be diverted into the illegal markets and abused by addicts.

522. With no doctors left to push opioids on the public, Melrose Park Clinic finally closed its doors for good on March 10, 2017.[182] But the damage had already been done.

523. In total, Prescriber Defendants have had a terrible impact on Plaintiffs' citizens

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[180] Bob Uphues, *Riverside Pain Doc's License Pulled By State*, Riverside-Brookfield Landmark (Nov. 8, 2016), http://www.rblandmark.com/News/Articles/11-8-2016/Riverside-pain-doc's-license-pulled-by-state/.

[181] Bob Uphues, *State Turns Up Heat On Riverside Pain Clinic*, Riverside-Brookfield Landmark (Dec. 6, 2016), http://www.rblandmark.com/News/Articles/12-6-2016/State-turns-up-heat-on-Riverside-pain-clinic/.

[182] Bob Uphues, *Riverside Pain Clinic Closing Its Doors*, Riverside-Brookfield Landmark (Mar. 9, 2017), http://www.rblandmark.com/News/Articles/3-9-2017/Riverside-pain-clinic-closing-its-doors/.

and Plaintiffs themselves, by dispensing enormous quantities of opioid prescriptions within, and to citizens within, Plaintiffs' communities over the past decade. Upon information and belief, Prescriber Defendants issued tens of thousands of bogus opioid prescriptions through the Melrose Park Clinic, including thousands to residents of Plaintiffs' communities.

524. The Prescriber Defendants knew or should have known that the extraordinary amounts of highly addictive controlled substances they were supplying to residents in and around Plaintiffs was not consistent with reasonable clinical practice, and was diverting opioids into the illegal market.

525. The Prescriber Defendants also knew or should have known that Plaintiffs and Illinois been experiencing an opioid epidemic of previously-unknown proportions, and that the cities, villages, towns, as well as the State, are experiencing excessively high rates of illegal use and diversion of prescription opioids.

526. Nonetheless, the Prescriber Defendants continued writing opioid prescriptions for virtually all comers, in order to continue reaping the profits they brought in.

527. The Prescriber Defendants knew that the volume and nature of their customers' requests for prescription opioids were highly suspicious and suggested that they were using and diverting opioids for illegal and/or unapproved uses. Despite this, the Prescriber Defendants undertook no efforts to change their practices. They sold the prescriptions for opioids, took the money, and that was that—even though the amounts of pills they were distributing to individual customers, and as a whole, was suspicious on its face.

528. As such, the Prescriber Defendants knowingly or negligently wrote suspicious prescriptions of opioids from January 2013 to March 2017, when the Melrose Park Clinic shut its doors. In addition, Giacchino knowingly or negligently wrote suspicious prescriptions of opioids,

and aided and abetted in doing so, from (upon information and belief) the time Illinois reinstated his suspended controlled substances license in June until March 2017, when the Melrose Park Clinic shut its doors.

529. The Prescriber Defendants received substantial profits for the controlled substances they provided to the residents of Plaintiffs' communities, but had no regard for the havoc they were wreaking on the cities, towns, and villages throughout Cook County.

V. Defendants' Conduct Has Fueled The Opioid Epidemic In Plaintiffs' Communities, Causing Them And Their Residents Extraordinary, Ongoing Harm.

530. If there is a single thread connecting Defendants' actions in their roles as manufacturers, distributors, and local dealers of prescription opioids, it is this: Defendants all repeatedly chose to maximize their profits at the expense of the welfare of Plaintiffs' communities and their citizens, allowing for knowing or negligent improper sales and diversion of massive quantities of opioids within these cities, towns, and villages, and across Illinois.

531. Upon information and belief, Manufacturer and Distributor Defendants have widely engaged in the same deceptive marketing and faulty distribution practices described herein in each of Plaintiffs' communities.

532. Opioids have had an acute impact in Illinois, where doctors prescribed enough opioids in 2016 to provide every other person with their own prescription—and still have enough left over for more than 850,000 people.[183] At least 1,947 deaths in Illinois were attributable to opioid overdosing in 2016 (accounting for 81 percent of all drug overdose deaths), a 41 percent increase over the prior year and a *303 percent* increase since 1999.[184] The Illinois Department of

[183] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates, 2016* (last visited Mar. 1, 2018), https://www.cdc.gov/drugoverdose/maps/rxstate2016.html.

[184] Henry J. Kaiser Family Foundation, *Opioid Overdose Deaths And Opioid Overdose Deaths As A Percent Of All Drug Overdose Deaths* (2015), *available at* http://kaiserf.am/2FHnxjI.

Public Health reports that more Illinoisans died from an opioid-related drug overdose (due to heroin and prescription opioids) in 2014 than from homicide or suicide, giving it—at the time—the third fastest-rising death rate from opioids in the nation.[185]

533. In addition, the number of infants diagnosed with Neonatal Abstinence Syndrome statewide grew to a record high of 373 in 2015 (although the Illinois Department of Public Health notes this likely underestimates its true incidence).[186]

534. At the local level, this crisis has manifested itself in rural, urban, and suburban communities alike across Illinois, including in Plaintiffs' communities.

535. Plaintiffs are all located in Cook County Illinois, except for Plaintiff City of Peoria, which is located in Peoria County.

536. Cook County had an opioid prescription rate of 41.3 prescriptions per 100 persons in 2016; down from a high of 47.5 prescriptions per 100 people in 2012, which was almost enough to provide every other person in Cook County with their own opioid prescription.[187] And suburban Cook County has seen its opioid-related overdose death rate rise to 13.7 per 100,000 in 2016, surpassing the 2015 national average of 10.4 per 100,000.[188]

537. Peoria County's opioid prescription rate has been even direr, which peaked at a

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[185] *Death Rate From Opioid Overdoses Rising In Illinois*, Il. News Network (Jan. 13, 2017), https://www.ilnews.org/news/health/death-rate-from-opioid-overdoses-rising-in-illinois/article_4d79650c-d1fa-539a-8fa7-0ba781151423.html.

[186] Ill. Dep't of Pub. Health, Neonatal Abstinence Syndrome Advisory Committee, *Annual Report to the General Assembly* 10, 12 (2017).

[187] *See* Centers for Disease Control and Prevention*, U.S. County Prescribing Rates, 2016* (last visited Mar. 4, 2018), https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html; Centers for Disease Control and Prevention*, U.S. County Prescribing Rates, 2012* (last visited Mar. 4, 2018), https://www.cdc.gov/drugoverdose/maps/rxcounty2012.html.

[188] Karen Kaplan, *Opioid Overdose Deaths Are Still Rising In Nearly Every Segment Of The Country, CDC Says*, L.A. Times (Mar. 29, 2018), http://www.latimes.com/science/sciencenow/la-sci-sn-opioid-overdose-deaths-20180329-htmlstory.html; Cook County Public Health, Epidemiology Brief: Opioid-Related Overdose Deaths In Cook County, IL, 2015, https://bit.ly/2GTUJaT (last visited Apr. 5, 2018).

rate of 94.6 opioid per 100 people in 2012—almost enough to give every person in Peoria County their own opioid prescription.[189]

538. Despite this, upon information and belief, many Cook and Peoria County residents who need addiction treatment do not receive it.

539. As a result of all of this, Cook County has experienced growing opioid overdose rates. 2015 saw 647 drug overdose deaths from opioids in Cook County.[190] Cook County Health and Hospitals System reported dealing with more than 5,000 opioid-related emergencies in 2016, a 400 percent increase since 2006.[191]

540. In Plaintiffs' communities, the opioid crisis' toll has been both emotional—impacting countless residents and their families—as well as financial, creating enormous pressure on law enforcement, municipal courts, fire department services, and more. It has also harmed private businesses throughout the community, contributing to absenteeism (*i.e.*, employees missing work) as well as presenteeism (*i.e.*, employees being functionally unable to perform their duties) in their local private sector.

541. And, as stated, the opioid epidemic has produced startling numbers of overdose deaths in Plaintiffs' communities. For every 20 opioid-related overdose deaths they have experienced, the services required to respond to and manage them cost Plaintiffs well over $700,000.[192] But this does not even begin to encompass the true costs of the opioid epidemic

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[189] *See* Centers for Disease Control and Prevention, *U.S. County Prescribing Rates, 2012* (last visited June 28, 2018), https://www.cdc.gov/drugoverdose/maps/rxcounty2012.html

[190] Cook County Public Health, Epidemiology Brief: Opioid-Related Overdose Deaths In Cook County, IL, 2015, https://bit.ly/2GTUJaT (last visited Apr. 5, 2018).

[191] Cook County Health and Hospital System, *Opioids*, http://www.cookcountyhhs.org/opioids/ (last visited Apr. 5, 2018).

[192] *See* Timothy J. Inocencio, et al., *The Economic Burden of Opioid-Related Poisoning In the United States*, 14 Pain Med. 1534, 1540 (2013) (average cost of responding to opioid overdose event is $38,968.)

caused by Defendants' actions for Plaintiffs, including criminal justice, medical, and workplace productivity costs in the community *because* of the crisis, as well as money spent by Plaintiffs voluntarily *in response* to the crisis.

542. As a direct and foreseeable consequence of Defendants' egregious conduct, Plaintiffs experienced a substantial increase in the number of opioids prescribed to residents, as well as opioid-related addiction, death, and overdose in recent years. At the same time, Plaintiffs have experienced more criminal activity that would have otherwise existed, but for opioid abuse and diversion of opioids into the black market. The devastating impact on the social fabric of Plaintiffs' communities causes them further economic harm, including costs related to police and fire responses to fatal and non-fatal opioid overdoses, as well as suspected overdoses.

543. Finally, Manufacturer and Distributor Defendants' conduct has harmed Plaintiffs by increasing the cost of providing health insurance to their employees. Like many municipal governments, Plaintiffs are self-insured entities, meaning that—instead of paying an insurance company to pay medical claims—Plaintiffs pay the claims themselves, using a third-party administrator to process the claims on its behalf. This includes the costs of employees' opioid prescriptions. Over the past two decades, Plaintiffs have been forced to cover an increasing number of opioid prescriptions being issued to its employees.

544. But for Defendants' conduct, the vast majority of these prescriptions would not have been issued, and Plaintiffs would not have had to pay to cover their cost. Furthermore, Plaintiffs overpaid for prescriptions that were not effective or safe for the advertised use.

545. Defendants' deceptive marketing, failure to monitor the opioid supply chain for obvious signs of diversion, and active participation in diversionary activities made such a state of affairs inevitable, giving rise to a drug epidemic the likes of which Plaintiffs, Illinois and the

nation have never seen.

COUNT I
PUBLIC NUISANCE
(On Behalf of All Plaintiffs As Against All Defendants)

546. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

547. Under Illinois law, a public nuisance is the "doing or the failure to do something that injuriously affects the safety, health or morals of the public, or works some substantial annoyance, inconvenience or injury to the public." *Burns v. Simon Properties Grp., LLP*, 2013 IL App (5th) 120325, ¶ 6, 996 N.E.2d 1208. (internal quotations omitted). A public nuisance claim must identify "(1) the existence of a public right; (2) a substantial and unreasonable interference with that right by the defendant; (3) proximate cause; and (4) injury." *Id.*

548. Plaintiffs' residents have a common right to be free from conduct creating an unreasonable risk of harm to public health, morals, comfort, welfare, and safety in their community, and to be free from conduct creating a disturbance and reasonable apprehension of danger to people and property.

549. As described herein, Defendants have created a continuing public nuisance in Plaintiffs' communities through their conduct, including Manufacturer Defendants' widespread campaign to aggressively and deceptively market prescription opioids beyond their approved uses; Distributor Defendants' intentionally and/or recklessly distributing and selling prescription opioids that they knew, or reasonably should have known, would be diverted to illegal and/or unapproved uses while illegally failing to put appropriate controls in place; and Prescriber Defendants' prescription of untold quantities of opioids under circumstances showing they knew, or should have known, that those opioids were being diverted to illicit and/or unapproved uses.

550. This conduct has not been insubstantial or fleeting, but has been of a continuing nature, requiring Plaintiffs to spend hundreds of thousands of dollars each year to abate the nuisance caused by Defendants' unreasonable actions through increased expenditures on law enforcement, medical and fire services, and much more.

551. Yet this conduct has had effects far broader and deeper than a mere budgetary strain: Plaintiffs' residents have endured the emotional and financial cost of caring for loved ones addicted to or injured by opioids; local employers have lost the value of once-productive and healthy employees suffering from the effects of opioid abuse; and opioid diversion into the black market has increased criminal activity, not only for prescription opioids but for heroin, as well.

552. Such elevated levels of crime and mounting abuse, addiction, overdose, and death due to prescription opioids has contributed to greater fear, discomfort, and inconvenience to the Plaintiffs' residents, on top of direct costs to Plaintiffs themselves.

553. This has caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort, and convenience of Plaintiffs' citizens, on every geographic and demographic level, such that the public nuisance created through Defendants' conduct has been (and is) commonly referred to as a "crisis" or "epidemic."

554. As such, Defendants have individually and collectively created an unreasonable public nuisance in Plaintiffs' communities.

555. Plaintiffs respectfully request this Court enter an order awarding judgment in their favor, including damages and reasonable attorneys' fees, and awarding Plaintiffs such other, further relief as this Court may deem just.

556. Plaintiffs also request this Court enter an order awarding declaratory relief by declaring that Defendants' activities constituted a public nuisance, enjoining Defendants from

engaging in any further activities constituting the public nuisance, and requiring Defendants to abate the public nuisance caused by their misconduct.

COUNT II
NEGLIGENCE
(On Behalf of All Plaintiffs As Against All Defendants)

557. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

558. In Illinois, a claim of negligence requires demonstrating the presence of a duty to a foreseeable plaintiff, a breach of said duty, and causation of damage to the plaintiff through the breach. *Guvenoz v. Target Corp.*, 2015 IL App (1st) 133940, ¶ 89, 30 N.E.3d 404. Furthermore, a violation of a statute or ordinance designed to protect human life creates a *prima facie* case of negligence, allowing for a claim of negligence per se when "(1) plaintiff is a member of the class of persons the statute or ordinance was designed to protect, (2) the injury is the type of injury that the ordinance was intended to protect against, and (3) the defendant's violation of the statute or ordinance was the proximate cause of the plaintiffs' injury." *Price ex rel. Massey v. Hickory Point Bank & Tr., Tr. No. 0192*, 362 Ill. App. 3d 1211, 1216, 841 N.E.2d 1084 (2006).

559. Defendants, as the manufacturers, distributors, and sellers of dangerous prescription opioids in Illinois, had an obligation to exercise due care in performing their duties. They utterly failed to do so.

560. Each Defendant owed a duty to Plaintiffs and the public health and safety within them, because the injury they caused through the deceptive marketing, illegal distribution, and reckless sale of dangerous Schedule II narcotics like prescription opioids was foreseeable to—and indeed, actually foreseen by—Defendants.

561. Reasonably prudent prescription opioid manufacturers would not have

misrepresented the risks of prescription opioids, nor overstated their benefits, through publications, CMEs, and other forms of direct and indirect marketing. Yet this is precisely what Manufacturer Defendants did by aggressively pushing highly addictive opioids for chronic non-cancer pain, despite repeated warnings from law enforcement and federal agencies of the unlawfulness and consequences of such actions (and omissions).

562. Reasonably prudent prescription opioid distributors would have implemented basic controls—required under Illinois law—to prevent opioid diversion in the supply chain. But Distributor Defendants failed to do this at all. Furthermore, Distributor Defendants failed to adhere to the legal duties imposed on them by statute, as distributors of a dangerous narcotic, by looking the other way while massive quantities of prescription opioids flowed into Plaintiffs' communities. *See* Ill. Admin. Code § 1510.50(i). This conduct endangered public health and violated numerous federal regulations—as incorporated into Illinois law—in ways contrary to the state legislature's goal of preventing the diversion of dangerous prescription drugs to illegal and unapproved uses.

563. As such, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of prescription opioids by filling unreasonably suspect orders over and over again, without imposing basic controls to monitor, identify, investigate, limit, and report suspicious orders for opioids. The very purpose of these duties was to prevent the harms that have directly followed: diversion of highly addictive drugs for illegal and/or non-approved purposes. Thus, the causal connection between Distributor Defendants' conduct and the ensuing harm was entirely foreseeable.

564. Prescriber Defendants, sold untold quantities of prescription opioids in the City under circumstances showing they knew, or should have known as reasonably prudent

prescribers, that those opioids were being diverted to illicit and/or unapproved uses. Prescriber Defendants engaged in the gross overprescription of opioids for years without implementing basic controls to prevent diversion, and ignored the clear signs of diversion. The very purpose of those controls (and attendant duties) was to prevent the harms that have directly followed: diversion of highly addictive drugs for illegal and/or non-approved purposes. Thus, the causal connection between the Prescriber Defendants' conduct and the ensuing harm was entirely foreseeable.

565. As a result of all Defendants' utter failure to take care in their role as prescription opioid manufacturers, distributors, and dealers, Plaintiffs have experienced, and continue to experience, an ongoing opioid epidemic that has brought extraordinary financial and social harm to the City.

566. Defendants acted with actual malice in taking these actions, as demonstrated by their willful flouting of basic duties and rules governing the marketing, distribution, and sale of prescription opioids.

567. As such, Defendants are each liable in tort for negligence. Additionally, Distributor Defendants have committed negligence per se by violating their duty as wholesale drug distributors to—among other things—not operate in a manner that would be injurious to public health.

568. Plaintiff seeks all legal and equitable relief allowed by law, including injunctive relief requiring Defendants to cease their negligent activity, restitution to Plaintiffs for the damages caused by Defendants' negligence, disgorgement of Defendants' profits caused by Defendants' negligence, entering a monetary judgment in favor of Plaintiffs and against Defendants for compensatory and punitive damages, and all other damages allowed by law.

COUNT III
FRAUDULENT MISREPRESENTATION
(On Behalf of All Plaintiffs As Against Manufacturer Defendants)

569. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

570. In Illinois, a cause of action for fraudulent misrepresentation requires "(1) a false statement of material fact; (2) known or believed to be false by the person making it; (3) an intent to induce the plaintiff to act; (4) action by the plaintiff in justifiable reliance on the truth of the statement; and (5) damage to the plaintiff resulting from such reliance." *Doe v. Dilling*, 228 Ill. 2d 324, 343, 888 N.E.2d 24 (2008).

571. Manufacturer Defendants' practices, as described in the Complaint, constitute fraudulent misrepresentation because the practices were intended to deceive doctors, consumers, other health care payors in Plaintiffs' communities, and Plaintiffs, and occurred in connection with the sale or advertisement of merchandise: that is, prescription opioids.

572. At all times relevant to the Complaint, Defendants, directly through their control of third parties, and by aiding and abetting third parties, committed fraudulent misrepresentation by making and disseminating deceptions and misrepresentations to promote the sale and use of opioids to treat chronic non-cancer pain, or by causing false statements about opioids to be made or disseminated in order to promote the sale and use of opioids to treat chronic non-cancer pain.

573. Manufacturer Defendants knew at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and failed to disclose material risks and were therefore likely to deceive prescribers, consumers, and other health care payors. In addition, they knew or believed that their marketing and promotional efforts created a false impression of the risks, benefits, and

superiority of their opioid products.

574. Manufacturer Defendants also engaged in the fraudulent conduct described above by acting in concert with third party Front Groups and KOLs to make false statements about Defendants' drugs' suitability for the treatment of chronic non-cancer pain. Manufacturer Defendants were aware of the nature of the statements made by KOLs and Front Groups, and yet provided them substantial assistance and encouragement by helping them develop refine and promote these false statements and distributing them to a broader audience.

575. Manufacturer Defendants also substantially encouraged the dissemination of these false statements by providing the Front Groups and KOLs with funding and technical support for the shared purpose of issuing misleading, pro-opioid messaging.

576. All of this conduct, separately and collectively, was intended to deceive residents of Plaintiffs' communities who used or paid for opioids for chronic pain; prescribers who prescribed opioids for chronic non-cancer pain; and other payors, including Plaintiffs, that covered the purchase of opioids for chronic non-cancer pain.

577. As a direct result of the foregoing acts, Manufacturer Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not made the false representations described herein. These false representations have damaged, and continue to damage, Plaintiffs through excess expenditures on providing basic services, as well as through costs paid for opioids they otherwise would not have purchased.

578. Plaintiffs respectfully request this Court enter an order awarding judgment in their favor for monetary damages, including reasonable attorneys' fees, and awarding Plaintiffs such other, further relief as this Court may deem just.

579. Plaintiffs also request this Court enter an order awarding declaratory relief by

declaring that Defendants' misrepresentations described herein were fraudulent and requiring Defendants to cease making such fraudulent misrepresentations in the future.

COUNT IV
INSURANCE FRAUD
(On Behalf of All Plaintiffs As Against Manufacturer Defendants)

580. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

581. 720 ILCS 5/17-10.5(a)(1) provides, in pertinent part, that a party commits insurance fraud when "he or she knowingly obtains … or causes to be obtained, by deception, control over the property of a … self-insured entity … by the making of a false claim or by causing a false claim to be made to a self-insured entity, intended to deprive a[] … self-insured entity permanently of the use and benefit of that property."

582. 720 ILCS 5/17-10.5(e)(1) provides that anyone who commits a violation of 720 ILCS 5/17-10.5(a)(1) "shall be civilly liable to the … self-insured entity that paid the claim … in an amount equal to either 3 times the value of the property wrongfully obtained … plus reasonable attorney's fees."

583. Throughout the relevant time period, Manufacturer Defendants, directly, through their control of third parties, and by acting in concert with those parties, knowingly caused false claims to be made to Plaintiffs' self-insured health plan, and—through their deception—obtained the property of Plaintiffs in payment for those false claims.

584. Manufacturer Defendants scheme caused prescribers to write prescriptions for opioids to treat chronic pain that were presented to the Plaintiffs' health plans for payment. Therefore, each claim for reimbursement to Plaintiffs for chronic opioid therapy is the direct result of Manufacturer Defendants false and deceptive marketing, which presented to prescribers

patently false and deceptive information about the risks, benefits, and superiority of opioids for the treatment of chronic non-cancer pain.

585. Plaintiffs only cover the cost of medical services and prescription drugs that are medically necessary, reasonably required, and prescribed for an FDA-approved used. Doctors, pharmacists, other health care providers and agents of Plaintiffs' health plans expressly or impliedly certified to Plaintiffs that opioids were medically necessary and reasonably required to treat chronic non-cancer pain, because they were influenced by the false and deceptive statements disseminated by Manufacturer Defendants about the risks, benefits, and superiority of opioids for treating chronic non-cancer pain.

586. These misrepresentations were material because, had Plaintiffs known of the false statements disseminated by Manufacturer Defendants, Plaintiffs would have refused to authorize payment for those opioid prescriptions as self-insured entities that directly cover the cost of their employees' prescription drugs.

587. As such, Manufacturer Defendants knowingly made, used, or caused to be made, false claims with the intent to induce Plaintiffs to approve and pay them.

588. As a result, Plaintiffs have been injured, and Manufacturer Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of 720 ILCS 5/17-10.5(a)(1) described herein.

589. Plaintiffs respectfully request that this Court enter an order awarding judgment in their favor, requiring Manufacturer Defendants to pay three times any money acquired as a result of the fraudulent conduct described above, ordering Manufacturer Defendants to pay reasonable attorneys' fees, and awarding Plaintiffs such other, further relief as this Court may deem just.

590. Plaintiffs also request this Court enter an order awarding declaratory relief by

declaring that Defendants' misrepresentations described herein were fraudulent and requiring Defendants to cease making such fraudulent misrepresentations in the future.

COUNT V
VIOLATIONS OF 815 ILCS 505/2
(On Behalf of All Plaintiffs As Against Manufacturer and Distributor Defendants)

591. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

592. The Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/2, provides:

> Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in section 2 of the 'Uniform Deceptive Trade Practices Act', approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration should be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act.

593. Throughout the relevant time period, Manufacturer Defendants, directly through their control of third parties, and/or by aiding and abetting third parties, violated the ICFA by engaging in unlawful, deceptive, and unfair acts and practices to promote the sale and use of opioids to treat chronic pain. These practices were intended to deceive consumers and Plaintiffs considering whether or not to purchase prescription opioids, as well as the doctors responsible for prescribing them.

594. Manufacturer Defendants directly, as well as indirectly through their control of third parties and/or aiding and abetting third parties, made and disseminated untrue, false, and misleading statements to consumers and prescribers in Plaintiffs' communities to promote the

sale and use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated to area prescribers and consumers to promote the sale and use of opioids for treating chronic non-cancer pain.

595. Manufacturer Defendants also made statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic pain. Manufacturer Defendants and their third-party allies repeatedly failed to disclose, or minimized, material facts about the risks, benefits and uses of opioids. Such material omissions were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opinions false or misleading regarding the risks benefits, and uses of opioids—particularly for the treatment of chronic non-cancer pain.

596. These false and misleading statements, and material omissions of fact, included, at minimum:

- Denying that pain patients would become addicted to opioids;
- Omitting that opioids are highly addictive and may result in overdose or death;
- Claiming that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;
- Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools;
- Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;
- Misleadingly promoting opioids as superior to competing analgesics, such as NSAIDs, including overstating the risks of NSAIDs and citing risks of NSAIDs without disclosing opioids' risks;
- Claiming opioids are an appropriate treatment for chronic pain, and failing to disclose the lack of long-term evidence for their use;
- Claiming chronic opioid therapy would improve patients' function and quality of life;
- Promoting opioids as able to provide lengthier periods of pain relief than was known to occur for many patients;
- Claiming abuse-deterrent opioids reduce addiction and abuse, and are safer than other opioids, and failing to disclose that they do not limit oral abuse, can be defeated with relative ease, and may increase overall abuse; and
- Omitting other material facts that deceived consumers and doctors through Manufacturer Defendants' affirmative representations to them, including other

adverse effects of opioid use.

597. Throughout the relevant time period, Manufacturer Defendants and the third parties they controlled made and disseminated such statements and material omissions through an array of marketing channels, including in-person detailing, speaker events, conferences, teleconferences, CMEs, studies, journal articles, supplements, advertisements, brochures, websites, and other patient and doctor education materials.

598. Manufacturer Defendants and the third-parties they controlled knew that these statements were untrue and misleading, or omitted material facts, when they made them, and knew they would likely deceive the public, and Plaintiffs, and cause them to purchase prescription opioids they otherwise would not have bought—that was the entire point.

599. Furthermore, the business practices Manufacturer Defendants engaged in during the relevant time period offended public policy, were immoral, unethical, oppressive, and unscrupulous, and have resulted in substantial injury to Plaintiffs and consumers in their communities that is not outweighed by a countervailing benefit to consumers or competition.

600. Among other things, these unfair practices included engaging in false and misleading drug marketing directly and through third parties; promoting the purported advantages of a Schedule II narcotic without substantial, credible scientific evidence to support their claims; failing to present a fair assessment of the risks, benefits, and uses of opioids to consumers; deliberately using unbranded marketing materials to evade FDA oversight and rules prohibiting deceptive marketing; and promoting their opioids for off-label uses.

601. This conduct offends the public policy in Illinois. As the legislature has decreed, "drug addiction [is] among the most serious health problems facing the people of the State of Illinois." 745 ILCS 35/2. But by engaging in the unfair conduct described above, Manufacturer

Defendants actively worked to conceal the risk of addition from Illinois patients, prescribers, and third-party payors in the hopes of selling ever-greater quantities of their products.

602. This conduct was also oppressive to Plaintiff. Plaintiffs put their trust in physicians to appropriately convey and balance the risks and benefits of various treatment options for their employees and residents of their communities. Physicians, in turn, are inclined to trust the advice of KOLs, Front Groups, and other seemingly independent sources of objective medical information. But by engaging in the conduct described herein, Manufacturer Defendants co-opted those sources of information in order to convince prescribing physicians—and through them, patients and Plaintiffs—that opioids were medically necessary to treat chronic non-cancer pain. This was especially so given Manufacturer Defendants' deliberate targeting of non-specialist physicians and non-physician prescribers, who lacked the time and expertise to evaluate the false, deceptive, and materially misleading claims being promoted to them.

603. Manufacturer Defendants conduct has grievously injured Plaintiffs, causing them not only to spend limited funds on providing excess municipal services in the opioid epidemic's wake, but causing them to spend money on opioid prescriptions that they otherwise would not have, but for Manufacturer Defendants' willing violations of public policy and oppressive behavior.

604. As such, Manufacturer Defendants have engaged in fraudulent, deceptive, unlawful, and unfair business practices in violation of Section 2 the ICFA.

605. In addition, the Distributor Defendants were in the position to implement effective business practices to guard against diversion of the highly-addictive opioid products they sell and distribute. They repeatedly purported to have done so. But those representations were untrue. Instead, they profited off the opioid epidemic by flouting anti-diversion laws, while burdening

Plaintiffs by their conduct and profiting from the sale of prescription opioids in quantities that far exceeded the number of prescriptions that could reasonably have been used for legitimate medical purposes, despite having notice or actual knowledge of widespread opioid diversion from prescribing records, pharmacy orders, field reports, and sales representatives. The Distributor Defendants' conduct constitutes an unlawful, fraudulent, and deceptive business practice.

606. Moreover, the Distributor Defendants' acts in violation of law are also business practices that constitute independent violations of the ICFA, including the Distributor Defendants' filling of suspicious or invalid orders for prescription opioids at both the wholesale and retail levels; failing to maintain effective controls against opioid diversion; failing to operate an effective system to disclose suspicious orders of controlled substances; failing to report suspicious orders of controlled substances; failing to reasonably maintain necessary records of opioid transactions; and deliberately ignoring questionable and/or obviously invalid prescriptions and filling them anyway—all while purporting to have world-class and compliant systems, controls, and practices.

607. As such, Distributor Defendants have engaged in fraudulent, deceptive, unlawful, and unfair business practices in violation of Section 2 the ICFA.

608. Manufacturer and Distributor Defendants' fraudulent, deceptive, unlawful, and unfair activity alleged herein caused Plaintiffs to incur substantial and continuing damages in their communities associated with the cost of opioids, as described herein, as well as the costs of providing opioids through their self-insured health plans.

609. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits, which they would not have

received if they had not engaged in the violations described herein.

610. No public policy justifies Defendants' misconduct, including the Manufacturer Defendants' decades' long misinformation campaign, which made it wholly unreasonable to expect that Plaintiffs could have avoided their injuries.

611. These acts or practices are unfair in that they offend public policy; are immoral, unethical, oppressive, or unscrupulous; and have resulted in substantial injury to Plaintiffs that is not outweighed by any countervailing benefits to consumers or competition. Plaintiffs request that this Court enter an order awarding judgment in Plaintiffs' favor to compensate them for injuries sustained as a result of Manufacturer and Distributor Defendants' consumer fraud and unfair practices, for restitution of any money acquired as a result thereof, and awarding such other relief as this Court may deem just.

612. Plaintiffs also request this Court enter an order awarding declaratory relief by declaring that Defendants' misrepresentations described herein were fraudulent and requiring Defendants to cease making such fraudulent misrepresentations in the future.

COUNT VI
UNJUST ENRICHMENT
(On Behalf of All Plaintiffs As Against All Defendants)

613. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

614. Under the doctrine of unjust enrichment, a party who receives a benefit must return it if retaining the benefit would be inequitable. Unjust enrichment requires a plaintiff to demonstrate that "defendant has unjustly retained a benefit to the plaintiffs' detriment, and that defendant's retention of the benefit violates the fundamental principles of justice, equity, and good conscience." *All. Acceptance Co. v. Yale Ins. Agency, Inc.*, 271 Ill. App. 3d 483, 492, 648

N.E.2d 971 (1995) (internal quotations and citations omitted).

615. Defendants' negligent, intentional, malicious, oppressive, illegal, and unethical acts, omissions, and wrongdoing entitle Plaintiffs to the disgorgement of profits received from all prescription opioid sales made therein during the relevant time period.

616. Defendants' manufacturing, marketing, distribution, and sale of prescription opioids was done in violation of the basic duties and rules governing these activities, unjustly enriching Defendants while causing extraordinary harm to Plaintiffs and their residents.

617. Plaintiffs, on their own and on behalf of their residents, conferred benefits on each Manufacturer Defendant, including payments for opioids manufactured by Manufacturer Defendants for sale in Plaintiffs' communities. These benefits were known to and accepted by each Manufacturer Defendant, and inured to each entity's profit. Retention of these benefits would be deeply inequitable in light of the false and misleading marketing and omissions of Manufacturer Defendants that contributed to and caused the opioid epidemic in Plaintiffs' communities. Thus, Manufacturer Defendants have been unjustly enriched by their deceptive practices.

618. Plaintiffs, on their own behalf and on behalf of their residents, conferred benefits on each Distributor Defendant, including payments for opioids distributed by each Distributor Defendant in Plaintiffs' communities. These benefits were known to and accepted by each Distributor Defendant, and inured to each entity's profit. Retention of these benefits would be deeply inequitable in light of Distributor Defendants' total failure to monitor, investigate, report, and halt orders of prescription opioids—that would have raised a red flag to even the most mildly scrupulous distributor of a Schedule II narcotics—and its resulting contribution to the opioid epidemic in Plaintiffs' communities. Distributor Defendants have thus been unjustly enriched by

neglecting their duty to distribute prescription opioids for effective uses and prevent diversion in the supply chain.

619. Plaintiffs, on their own behalf and on behalf of their residents, conferred benefits on the Prescriber Defendants, including payments for medical care services in Plaintiffs' communities. These benefits were known to and accepted by the Prescriber Defendants, and inured to their benefit. Retaining these benefits would be deeply inequitable in light of the Prescriber Defendants' utter failure to police their sales of prescription opioids for obvious signs of diversion and abuse, in a way that has contributed to the opioid epidemic in Plaintiffs' communities. Thus, Prescriber Defendants have been unjustly enriched by and through their actions.

620. Plaintiffs' unprecedented opioid epidemic has cost them hundreds of thousands of dollars in health insurance and municipal services costs. The unjust enrichment of the Defendants is directly related to the damage, loss, and detriment to Plaintiffs caused by Defendants' marketing tactics, supply chain management practices, and prescribing practices.

621. It would be inequitable under these circumstances for Defendants to be allowed to retain these benefits without compensating the Plaintiffs for their value. The enrichment Defendants experienced was without justification and Plaintiffs lack a remedy provided by law.

622. As such, Plaintiffs respectfully requests this Court award judgment in their favor, including declaratory relief that Defendants were unjustly enriched by their conduct described above, injunctive relief requiring Defendants to cease engaging in such conduct, ordering Defendants to disgorge their unjustly-obtained profits to Plaintiffs, and awarding such other relief as this Court may deem just.

623. Plaintiffs also request this Court enter an order awarding declaratory relief by

declaring that Defendants' misrepresentations described herein were fraudulent and requiring Defendants to cease making such fraudulent misrepresentations in the future.

COUNT VII
CIVIL CONSPIRACY
(On Behalf of All Plaintiffs As Against Distributor Defendants)

624. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

625. A civil conspiracy is a combination of two or more persons to accomplish an unlawful end or to accomplish a lawful end by unlawful means. *Adcock v. Brakegate, Ltd.*, 164 Ill. 2d 54, 62, 645 N.E.2d 888 (1994).

626. Manufacturer Defendants acted tortiously in concert with each other in pursuit of a common goal: the pursuit of ever-greater profits from the sale of prescription opioids in Plaintiffs' communities through a campaign of misinformation and turning a blind eye to massive diversion of dangerous narcotics.

627. Manufacturer Defendants agreed to, and did, pursue a common strategy of fabricating a market for long-term use of opioids by minimizing the risks of opioids, overstating their efficacy, and denigrating competing products. This agreement is evidenced by Manufacturer Defendants co-promotion and sponsorship of KOLs and Front Groups who promulgated their misleading information about opioids. As part of their agreements with one another, Manufacturer Defendants agreed with Front Groups that they would deceptively promote the risks, benefits, and superiority of opioid therapy, and that Manufacturer Defendants would provide support for Front Group's deceptive statements, including the dissemination of misleading messaging about opioids.

628. On information and belief, Manufacturer Defendants agreed to, and did, engage in

a civil conspiracy that necessarily required—as a consequence of their conduct—creating a public nuisance, making fraudulent misrepresentations, committing insurance fraud on Plaintiffs, violating the ICFA, and committing unjust enrichment through the unlawful distribution and diversion of opioids into Plaintiffs' communities and actively working to broaden the market for prescription opioids on false grounds. Manufacturer Defendants work to weaken regulatory enforcement of pharmaceutical distribution and are highly coordinated through trade groups such as the Pain Care Forum. Given the level of coordination of their legal activities, and the scale of their illegal activities, the Manufacturer Defendants intended, agreed, and knew that the public would be misled about the risks and benefits of opioids.

629. The particular dates and times of Manufacturer Defendants' agreement cannot be known because this information is known only to Defendants. Indeed, this information has been hidden, because obfuscation and secrecy are essential to the success of the conspiracy.

630. Manufacturer Defendants unlawfully marketed prescription opioids in Plaintiffs' communities and throughout Illinois in furtherance of this conspiracy.

631. Their conduct was malicious, purposeful, intentional, and unlawful, and proximately caused (or substantially contributed to) the direct and foreseeable consequences of this conduct: a boom in opioid abuse, addiction, overdose, and death in Plaintiffs' communities, and the attendant financial costs to Plaintiffs of responding to these ongoing issues.

632. Plaintiffs respectfully request this Court enter an order awarding judgment in their favor to compensate them for injuries sustained as a result of Manufacturer Defendants' misconduct, for restitution of any money acquired as a result thereof, and awarding such other relief as this Court may deem just.

633. Plaintiffs also request this Court enter an order awarding declaratory relief by

declaring that Manufacturer Defendants' activities constituted a civil conspiracy, enjoining Manufacturer Defendants from engaging in any further activities constituting civil conspiracy, providing injunctive relief requiring Manufacturer Defendants to abate any harm caused by their civil conspiracy.

COUNT VIII
CIVIL CONSPIRACY
(On Behalf of All Plaintiffs As Against Prescriber Defendants)

634. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

635. A civil conspiracy is a combination of two or more persons to accomplish an unlawful end or to accomplish a lawful end by unlawful means.

636. Prescriber Defendants acted tortiously in concert with each other in pursuit of a common goal: the pursuit of ever-greater profits from the sale of prescription opioids in Plaintiffs' communities through by willfully turning a blind eye to massive diversion of dangerous narcotics happening right under their noses.

637. Prescriber Defendants agreed to, and did, pursue a common strategy of willfully prescribing enormous quantities of opioids to consumers in Plaintiffs' communities without performing basic due diligence, either as doctors and/or clinic operators. Their "clinic" was, in reality, a pill mill where the only qualification needed to obtain opioids was sufficient cash. This agreement is evidenced by Prescriber Defendants' group operation of Melrose Park Clinic in Riverside beginning in 2013, numerous instances of wanton opioid overprescribing documented through investigations by the IDFPR, the uniformity of result following the IDFPR's investigations (*i.e.*, the suspension of Defendant McMahon and Madison's medical licenses), and prior instances of precisely the same conduct engaged in by the Melrose Park Clinic's

"administrator," Defendant Giacchino.

638. Prescriber Defendants agreed to, and did, engage in a civil conspiracy that necessarily required—as a consequence of their conduct—creating a public nuisance, engaging in negligent behavior that injured Plaintiffs, and committing unjust enrichment. It also involved, as to Defendants McMahon and Madison post-2013, violating the Illinois Medical Practice Act's prohibition on prescribing or distributing a controlled substance for anything other than a medically accepted therapeutic purpose, and engaging in dishonorable, unethical and unprofessional conduct in a manner likely to harm the public. 226 ILCS 60/22(A)(5), (17).

639. Prescriber Defendants managed, operated, and worked at the Melrose Park Clinic, and through their work their distributed vast quantities of prescription opioids to the cash-bearing pubic in furtherance of this conspiracy.

640. At all times, Prescriber Defendants' conduct was malicious, purposeful, intentional, and unlawful, and proximately caused (or substantially contributed to) the direct and foreseeable consequences of this conduct: a boom in opioid abuse, addiction, overdose, and death in Plaintiffs' communities, and the attendant financial costs to Plaintiffs of responding to these ongoing issues.

641. Plaintiffs respectfully request this Court enter an order awarding judgment in their favor to compensate them for injuries sustained as a result of Prescriber Defendants' misconduct, for restitution of any money acquired as a result thereof, and awarding such other relief as this Court may deem just.

642. Plaintiffs also request this Court enter an order awarding declaratory relief by declaring that Prescriber Defendants' activities constituted a civil conspiracy, enjoining Prescriber Defendants from engaging in any further activities constituting civil conspiracy,

providing injunctive relief requiring Prescriber Defendants to abate any harm caused by their civil conspiracy.

COUNT IX
DECEPTIVE TRADE PRACTICES
(On Behalf of Plaintiff Orland Park As Against Manufacturer Defendants)

643. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

644. Orland Park Village Code ("OPVC") § 7-10-5 provides, in pertinent part, "[n]o person shall act, use or employ any deception, fraud, false pretense, false promise, misrepresentation, or to conceal, suppress, or omit any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale for cash or on credit or the advertisement of any merchandise, whether or not any person has in fact been misled."

645. OPVC defines "merchandise" as "any objects, wares, goods, commodities, intangibles, real estate or services." § 7-10-1.

646. As described above, Manufacturer Defendants have engaged in deceptive trade practices in Orland Park that—through their acts, omissions, and practices—have violated numerous provisions of the Orland Park Village Code. Manufacturer Defendants' violations include, but are not limited to:

- Representing that merchandise or services are of a particular standard, grade or quality, or that merchandise is represented to be of a particular style or model, if they are of another. OPVC § 7-10-5(2).

- Causing likelihood of confusion or misunderstanding concerning the source, sponsorship, approval or certification of merchandise or services. OPVC § 7-10-5(6).

- Represents that merchandise or services have sponsorship, approval, characteristics, ingredients, uses, benefits or qualities that they do not have…

OPVC § 7-10-5(8).

- Fails to state a material fact, if such failure tends to deceive or mislead. OPVC § 7-10-5(9).

647. Manufacturer Defendants have aimed the following deceptive practices, among others, at both prescribing physicians and consumers in Orland Park:

- Denying that pain patients would become addicted to opioids;
- Omitting that opioids are highly addictive and may result in overdose or death;
- Claiming that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;
- Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools;
- Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;
- Misleadingly promoting opioids as superior to competing analgesics, such as NSAIDs, including overstating the risks of NSAIDs and citing risks of NSAIDs without disclosing opioids' risks;
- Claiming opioids are an appropriate treatment for chronic pain, and failing to disclose the lack of long-term evidence for their use;
- Claiming chronic opioid therapy would improve patients' function and quality of life;
- Promoting opioids as able to provide lengthier periods of pain relief than was known to occur for many patients;
- Claiming abuse-deterrent opioids reduce addiction and abuse, and are safer than other opioids, and failing to disclose that they do not limit oral abuse, can be defeated with relative ease, and may increase overall abuse; and
- Omitting other material facts that deceived Orland Park consumers and doctors through Manufacturer Defendants' affirmative representations to them, including other adverse effects of opioid use.

648. All of the acts described above were willful and continuous, and through them have caused (and continue to cause) Orland Park and its residents significant injury.

649. As such, Manufacturer Defendants have violated the OPVC, and through it, OPVC § 7-10-5.

650. Section 6 of the OPVC imposes statutory damages, for "[a]ny person, firm, corporation or entity who violates, disobeys, omits, neglects, refuses to comply with or who resists enforcement of any of the provisions of this Chapter," of not less than $75 and not more

than $1,000 per violation. OPVC § 7-10-6; Appx. B.

651. Because Manufacturer Defendants have willfully and continuously violated the Orland Park Village Code, they are liable for fines on not less than $75 and not more than $1,000 per violation, as to be determined by the trier of fact.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs City of Harvey, Village of Broadview, Village of Chicago Ridge, Village of Dolton, Village of Hoffman Estates, Village of Maywood, Village of Merrionette Park, Village of North Riverside, Village of Orland Park, City of Peoria, Village of Posen, Village of River Grove, Village of Stone Park, and Orland Fire Protection District respectfully request that this Court enter an Order:

A. Declaring that Defendants have created a public nuisance;

B. Directing Defendants to abate the public nuisance that they created and pay all appropriate damages;

C. Declaring that Defendants have acted negligently;

D. Directing Defendants to pay all damages caused by their negligent actions to Plaintiffs;

E. Declaring that Manufacturer Defendants have engaged in fraudulent misrepresentation;

F. Directing Manufacturer Defendants to pay all damages caused by their fraudulent misrepresentations;

G. Declaring that Manufacturer Defendants have committed insurance fraud;

H. Directing Manufacturer Defendants to pay three times the value of the property unlawfully obtained, or twice the value of the property attempted to be obtained, whichever is

greater;

I. Declaring that Defendants have engaged in unlawful, fraudulent, and deceptive acts in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act;

J. Directing Defendants to pay all damages caused by their unlawful, fraudulent, deceptive, and unconscionable business practices to Plaintiffs, including restitution of any money acquired as a result thereof;

K. Declaring that Defendants have been unjustly enriched by their conduct;

L. Directing Defendants to pay restitution of all benefits and disgorge all profits unjustly retained to Plaintiffs;

M. Declaring that Defendants have engaged in an unlawful civil conspiracy;

N. Directing Defendants to pay all damages caused by their civil conspiracy to Plaintiffs;

O. Declaring that Defendants committed deceptive trade practices in violation of the Orland Park Village Code;

P. Directing Defendants to pay all applicable statutory damages caused by their violation of the Orland Park Village Code;

Q. Awarding treble and punitive damages as appropriate;

R. Awarding injunctive relief as necessary to protect the interests of Plaintiffs;

S. Awarding Plaintiffs their reasonable litigation expenses and attorneys' fees;

T. Awarding Plaintiffs pre- and post-judgment interest to the extent allowable; and

U. Award any and all other relief the Court deems appropriate and just.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury in this matter.

Respectfully submitted,

CITY OF HARVEY, VILLAGE OF BROADVIEW, VILLAGE OF CHICAGO RIDGE, VILLAGE OF DOLTON, VILLAGE OF HOFFMAN ESTATES, VILLAGE OF MAYWOOD, VILLAGE OF MERRIONETTE PARK, CITY OF NORTH RIVERSIDE, VILLAGE OF ORLAND PARK, CITY OF PEORIA, VILLAGE OF POSEN, VILLAGE OF RIVER GROVE, VILLAGE OF STONE PARK, and ORLAND FIRE PROTECTION DISTRICT,

Dated: July 19, 2018

By: /s/ Benjamin H. Richman
One of Plaintiffs' Attorneys

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