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

INTERGOVERNMENTAL RISK MANAGEMENT AGENCY and INTERGOVERNMENTAL PERSONNEL BENEFIT COOPERATIVE,

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 PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., NORAMCO, 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, AMERICAN ACADEMY OF PAIN MEDICINE, AMERICAN GERIATRIC SOCIETY, AMERICAN PAIN SOCIETY, AMERISOURCEBERGEN CORPORATION, CARDINAL HEALTH, INC., MCKESSON CORPORATION, PAUL MADISON, and JOSEPH GIACCHINO,

Defendants.

Case No. 2018CH12828

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Intergovernmental Risk Management Agency ("IRMA") and Intergovernmental Personnel Benefit Cooperative ("IPBC") bring this Complaint and Demand for Jury Trial against manufacturers, distributors, and prescribers of opioids, alleging as follows:

NATURE OF THE ACTION

1. The country is currently facing the most calamitous public health crisis in its modern history—the over-prescription, misuse, and abuse of opioids.

2. Prescription opioids are highly addictive narcotics, which is why the federal government has regulated them since 1970 as largely Schedule II controlled substances.[1] Today, they have unfortunately become the most common means of treatment for chronic pain.[2]

3. In 1997, doctors wrote 670,000 prescriptions for OxyContin (a Schedule II narcotic) to treat non-cancer pain; in 2002, doctors wrote 6.2 million.[3] Sales of prescription opioids in general nearly quadrupled in the United States from 1999 to 2014.[4] This spike does not reflect an epidemic of pain, but an epidemic of over-prescribing opioids. For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, as the use of NSAIDs or acetaminophen—common non-opioid pain medications—declined.

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[1] Controlled substances are categorized into five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. Schedule II controlled substances have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin), fentanyl (Duragesic, Actiq, Fentora), methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone). Some opioids, including forms of hydrocodone and codeine combined with other drugs, were previously categorized as Schedule III drugs, which have a lower potential for abuse. However, in October 2013, the FDA reclassified all medications that contain hydrocodone from Schedule III to Schedule II. *See* 21 C.F.R. § 1308. Illinois also classifies hydrocodone and related opiates as Schedule II drugs under the Illinois Controlled Substances Act. 720 ILCS 570/206(b)(1).

[2] Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

[3] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 90 Am J. Pub. Health 221 (2009).

[4] *Prescription Opioid Data*, CDC, https://www.cdc.gov/drugoverdose/data/prescribing.html (last visited Oct. 9, 2018).

4. The dramatic spike in opioid prescriptions to treat chronic pain has resulted in a population of addicts desperate to satisfy their cravings: it has become, according to the U.S. Centers for Disease Control and Prevention (CDC), a "public health epidemic."[5]

5. A 2016 CDC study estimated the national economic impact of prescription opioid overdoses, abuse, and dependence to be $78.5 billion dollars annually, including $42 billion in lost productivity, $26.1 billion in health insurance, $7.6 billion in criminal justice, and $2.8 billion in substance abuse treatment.[6]

6. Plaintiffs IRMA and IPBC are two intergovernmental cooperative agencies that help Illinois municipalities and other Illinois-based public entities cover their employees' healthcare needs. As an alternative to the commercial insurance market, IRMA and IPBC are both highly regarded for the dramatic savings they provide their members through their insurance and risk management programs, which are uniquely tailored for low budget, high risk-facing public entities.

7. Opioid use has become common among workers injured at work while they are recovering from an injury. A study by the National Council on Compensation Insurance concluded that in 2011, approximately 38% of pharmacy costs in workers' compensation were for opioids and opioid combinations, amounting to approximately $1.4 billion.

8. The costs of long-term opioid use are not limited to the costs of opioid prescriptions. Workers also receive temporary disability benefits for periods when they cannot work while recovering from injuries. A recent study suggests that extensive opioid prescriptions

[5] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), https://www.cdc.gov/washington/testimony/2014/t20140429.htm.

[6] C. Florence, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and* Dependence in the United States, 54(10) Medical Care 901 (Oct. 2016).

causes injured workers to incur longer durations of temporary disability leave.[7] The study concluded that an injured worker living in a community with a higher local rate of longer-term opioid prescribing is more likely to spend more time off work than a worker who experiences the same injury in a low-prescription area.

9. The employees from IRMA and IPBC's member entities are at the epicenter of the national opioid public health crisis. In 2015, 8 million opioid prescriptions were filled in Illinois (60 opioid prescriptions per 100 persons).[8]

10. As providers of insurance-related services, IRMA and IPBC have had to shoulder substantial and unusual costs resulting from the far-reaching impact of the over-prescription and overuse of opioids. In addition to the unanticipated burden of covering opioid prescription costs, IRMA and IPBC have expended vast funds on hospitalizations due to overdose, addiction treatment services, and overdose reversal medications. IRMA has likewise paid out millions of dollars in employee disability benefits to injured workers who received long-term opioid prescriptions to treat chronic pain, a treatment option which, as detailed below, has no scientific justification.

11. The story of how these highly addictive, dangerous narcotics crept into the accepted standards of care for treating chronic, non-cancer pain is detailed herein. Weaving throughout it is a chain of indifferent profiteering carried out on both the demand side by the drug manufacturers (with help from front advocacy groups) and the supply side by the drug distributors and certain prescribers.

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[7] David Neumark, Bogdan Savych, Randall Lea, *The Impact of Opioid Prescriptions on Duration of Temporary Disability*, Workers Compensation Research Institute (Mar. 6, 2018).

[8] Xponent, IMS Health, *State and National Totals of Filled Prescriptions: All Opioid Analgesics* (2016), https://www.mag.org/georgia/UploadedFiles/prescriptions-filled-chart.pdf.

12. On the demand side, the drug companies that manufacture, market, and sell opioids (the "Manufacturer Defendants") have long known that opioids are addictive and subject to abuse, particularly when used long-term for chronic, non-cancer pain. In order to create maximum demand for them, Manufacturer Defendants needed to reverse the medical understanding of opioids so that prescribing them long-term to treat chronic pain would be commonplace. They also needed to bury the unfavorable research about opioid addiction and abuse so that consumers perceived opioids as a safe and medically-acceptable way to treat chronic pain.

13. For decades, Manufacturer Defendants deployed an intricate and highly misleading misinformation campaign that overstated the benefits and downplayed the risks of long-term opioid treatment for chronic pain. This marketing scheme—designed, supported, and executed by Manufacturer Defendants—was devised to push increased opioid sales and expand the chronic pain market. Through their sales representatives, physician speakers, and front advocacy groups—among other aggressive marketing tactics—Manufacturer Defendants convinced doctors in Illinois (and nationwide) to prescribe opioids for common chronic pains, such as back pain or arthritis, even though they knew that opioids were highly addictive, susceptible to abuse, and not effective for these uses.

14. Defendants American Academy of Pain Medicine ("AAPM"), American Geriatric Society ("AGS"), and American Pain Society ("APS") (collectively referred to as "Front Group Defendants"), who injunctive relief is sought through this Complaint, worked with the Manufacturing Defendants to promote opioids to doctors and patients, including elderly patients, as appropriate and safe for long-term use to treat chronic pain such as back pain. With significant financial support from and the direct involvement of the Manufacturer Defendants, the Front

Group Defendants published treatment guidelines, continuing medical education programs, and other materials that deceptively promoted the use of opioids for chronic pain. Because of their seeming objectivity and non-profit, public service missions, their promotional activity carried greater weight and buttressed Manufacturing Defendants' own marketing.

15. The marketing scheme worked: because of Defendants' misleading and unfair marketing, doctors in Illinois (and nationwide) prescribed prolific volumes of opioids to treat chronic pain. Opioids are now the most prescribed class of drugs, generating $11 billion in revenue for drug companies in 2014, alone. In an open letter to physicians in August 2016, then-U.S. Surgeon General expressly connected this "urgent health crisis" 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."[9]

16. The supply scheme was perpetrated by the drug distribution companies, which have a duty to monitor and report "red flags" in opioid ordering in order to prevent the diversion and misuse of prescription opioids (the "Distributor Defendants"). Instead of performing their duty as gatekeepers in the supply chain, Distributor Defendants have thrown open the gates and looked the other way, supplying opioids in quantities throughout Illinois (and nationwide) that they knew or should have known exceed any legitimate market for the drugs.

17. Finally, at the end of the opioid supply chain, as it pertains to this lawsuit, Defendants Paul Madison and Joseph Giacchino ("Prescriber Defendants") took full advantage of the sham market for long-term opioid treatment and worked around the clock to prescribe opioids to anyone who came through the door of their clinic in Riverside, Illinois—whether or

[9] Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, *available at* https://www.aafp.org/patient-care/public-health/pain-opioids/turn_the_tide.html.

not they had a valid need for them or presented any number of patently suspicious traits. The pill mill they operated distributed directly to individuals under IPBC coverage, much less thousands upon thousands of prescriptions to countless residents in IPBC and IRMA member communities (including the Village of Riverside, which is a member of IRMA), driving up the prescription rates in IPBC and IRMA's member communities and, as explained herein, causing injured workers to spend more time off work at IRMA's expense.

18. As a direct and foreseeable result of Defendants' conduct, IRMA and IPBC have wasted millions of dollars in dividends and reserve funds to pay out claims for prescriptions, medical treatment, and extended disability benefits resulting from long-term and unnecessary opioid treatment. The focus of this lawsuit is on how these costs could and should have been avoided, if not for various actors in the pharmaceutical company who chose to maximize their own profits at the expense of patient welfare.

19. Defendants' role in creating this public health crisis—individually and/or in concert with the various third parties they engaged to do their bidding—has violated and continues to violate state and common law, including:

- **815 ILCS 505/2,** in that Defendants engaged in fraudulent and unfair acts and practices in their promotion of opioids to treat chronic pain.

- **720 ILCS 5/170-10.5**, in that Defendants knowingly obtained, attempted to obtain, or caused to be obtained, by deception, control over the property of a self-insured entity (Plaintiffs) by making a false claim or by causing a false claim to be made to Plaintiffs, intending to deprive Plaintiffs permanently of the use and benefit of that property.

- **Civil conspiracy**, in that Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

- **Public nuisance**, in that Defendants' acts and omissions have substantially and unreasonably interfered with the health, safety, peace, comfort, and convenience of the general public, have obstructed or caused

inconvenience or damage to the public in the exercise of rights common to all, and/or caused substantial annoyance, inconvenience or injury to the public by creating a public health epidemic in Plaintiffs' member communities.

- **Unjust enrichment**, in that Defendants have unjustly retained a benefit to Plaintiffs' detriment, and Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

20. Plaintiffs bring this action to obtain redress, including injunctive relief, for these violations.

JURISDICTION AND VENUE

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

22. 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.

23. Venue is proper in Cook County because Defendants have conducted business transactions in Cook County, the majority of IRMA and IPBC's members are located in Cook County, and the causes of action arose, in substantial part, in Cook County.

PARTIES

24. 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

25. Plaintiff IRMA is a member-owned municipal risk pool representing various municipalities and public entities in northeastern Illinois. At all relevant times, IRMA's office and principal place of business has been located in Cook County, Illinois.

26. Plaintiff IPBC is a member-owned municipal risk pool representing various municipalities and public entities across Illinois. At all relevant times, IPBC's office and principal place of business has been located in Oak Brook, Illinois.

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 in 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. 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. Allergan PLC ("Allergan") is a public company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis Kadian LLC ("Actavis Kadian") is a Delaware corporation and subsidiary of Allergan, with its principal place of business in

Morristown, New Jersey. Actavis Elizabeth, LLC ("Actavis Elizabeth") is a Delaware corporation with its principal place of business in Elizabeth, New Jersey. Actavis PLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis PLC acquired Allergan in March 2015, and the company took the Allergan name. Before that, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") acquired Actavis PLC 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.

30. Prior to 2016, Allergan was the corporate parent of Actavis, Actavis PLC, Actavis Pharma, Actavis Elizabeth, Actavis Kadian, Watson Pharmaceuticals, and Watson Labs (together, the "Actavis Generics"). In 2016, Teva USA wholly acquired the Actavis Generics. Teva Ltd. now exercises control over these marketing and sales efforts, and the Actavis Generics products ultimately inure to its benefit. The Actavis Generics are referred to as "Actavis" herein, unless otherwise specified.

31. 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, and the company corresponds with the FDA regarding Janssen's products. 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., ("Janssen 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, Noramco, Ortho-McNeil-Janssen, and Janssen Pharmaceutica—are referred to herein as "Janssen" unless otherwise specified.

32. Endo Health Solutions, Inc. ("Endo Health Solutions") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. d/b/a Endo Generic Products ("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. Par Pharmaceutical Companies, Inc. d/b/a Par Pharmaceutical ("Par Pharmaceutical) is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Endo Health Solutions acquired Par Pharmaceutical in September 2015. Endo Health Solutions now exercises control over these marketing and sales efforts, and the Par Pharmaceutical products ultimately inure to its benefit. Endo Health Solutions, Endo Pharmaceuticals, and Par Pharmaceutical are collectively referred to herein as "Endo," unless otherwise specified.

33. 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.

34. Collectively, Purdue, Cephalon, Endo, Janssen, 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.

Front Group Defendants

35. The American Academy of Pain Medicine (AAPM) is a 501(c)(6) tax exempt organization with its principal place of operation in Chicago, Illinois. According to its more recent Form 990 filing with the Internal Revenue Service, AAPM's purpose is to "optimize the health of patients and eliminate the major public health problem of pain by advancing the practice and the specialty of pain medicine."

36. The American Geriatrics Society (AGS) is a 501(c)(3) tax exempt organization with its principal place of operations in New York, New York. According to its more recent Form 990 filing with the Internal Revenue Service, AGS's purpose is to "[i]mprove the health, independence[, and] quality of life of all older people[.]"

37. The American Pain Society (APS) is a 501(c)(3) tax exempt organization with its principal place of operations in Chicago, Illinois. According to its most recent Form 990 filing with the Internal Revenue Service, APS's purpose is to "increase the knowledge of pain and transform public policy and clinical practice."

Distributor Defendants

38. 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.

39. 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.

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

41. Together, AmerisourceBergen, Cardinal Health, and McKesson collect about 85 percent of the revenues for prescription drugs distributed in the United States.

42. 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

43. Defendants Paul Madison and Joseph Giacchino (together, "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, he and Madison wrote opioid prescriptions for the clinic's patients during the entire time of its operation.

44. 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.

45. As of today, both 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.[10] 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. For Years, IRMA and IPBC Have Paid For Non-Medically Necessary Opioid Prescriptions And Their Attendant Costs.

A. IRMA's Workers' Compensation Coverage.

46. IRMA is a risk management agency responsible for managing the workers' compensation claims for 72 municipal entities in northeastern Illinois.

47. IRMA evolved from a seminar held in 1976 in which 69 northern Illinois cities met to discuss municipal insurance problems, namely that self-insurance is not practical for small municipalities that lack adequate funds and employees over which to spread large risks. A committee's study of the matter led to the establishment of IRMA in 1979.

48. IRMA was the first municipal risk pool in Illinois. Since its first year in operation, the program has received national attention for both its dramatic savings for members and for its improved insurance and risk management programs.

49. IRMA's inception—and early success—sparked a national trend of other cooperative insurance pools and risk management organizations being established by governmental employers. Today, IRMA remains highly regarded as an alternative to the commercial insurance market which has served its cost-cutting purpose rather well.

50. Through IRMA, participating municipalities have extensive loss prevention and risk management programs, expert claims handling, and receive interest on invested pool

[10] *See Giacchino v. Ill. Dep't of Fin. & Prof'l Regulation, et al.*, 2013 IL App (1st) 122694-U, ¶ 74.

contributions. IRMA maintains its own professional staff, including risk managers, claims adjusters, and legal counsel.

51. The 72 members that comprise IRMA are mainly municipalities and special service districts in northeastern Illinois.

52. IRMA provides its members with a comprehensive workers' compensation program, including payment of all medical bills associated with work-related injuries—including prescription drug benefits—and temporary total disability benefits.

53. When a member's employee is injured on the job, he or she may file a claim for workers' compensation; the member employer submits the claim to IRMA to determine if the injury is work-related, in which case IRMA pays the employees' medical, temporary total disability, and permanent partial disability payments. For prescription drug coverage, doctors submit claims directly to IRMA for the costs associated with the prescriptions, including office visits and toxicology screens.

54. IRMA's workers' compensation program covers *all* medical costs associated with opioid treatment for work-related injuries, including services rendered in response to any adverse outcomes from chronic opioid use, such as addiction treatment.

55. For many years, injured workers covered by IRMA's workers' compensation coverage were prescribed opioids to treat non-cancer, chronic pain arising from workplace injuries.

56. IRMA also covers a portion of the temporary disability benefits that workers receive while they are away from work recovering from an injury. Temporary disability benefits often end when workers return to work, when they are released to work by their doctor, when they reach maximum medical improvement, or when they receive permanent partial disability

benefits and/or a lump-sum settlement.

57. IRMA uses CorVel, a medical management vendor, to manage medical benefits under the workers' compensation program, including performing a utilization review to ensure that only those medical costs that are necessary and required to be paid by the Illinois Workers' Compensation Act are actually paid.

58. The Illinois Workers' Compensation Act requires employers to pay for "all the necessary first aid, medical and surgical services, and all necessary medical, surgical and hospital services thereafter incurred, limited, however to that which is reasonably required to cure or relieve from the effects of the accidental injury." 820 ILCS 305/8(a).

59. Thus, IRMA's workers' compensation program is obligated to cover all "medically necessary" and "reasonably required" treatment arising from a compensable work-related injury.

B. IPBC's Health Insurance Coverage.

60. Similarly, IPBC is a self-insured intergovernmental pool responsible for providing health benefits to the employees and retirees (and in many instances, their dependents) of 131 municipal and other local governments throughout Illinois.

61. IPBC was established in 1979 by Chicago-area municipalities to administer the personnel benefit programs that the participating members offered to their employees.

62. Similar to IRMA's risk pooling, each IPBC member pays monthly into a pool and shares the claims experience together with other members through banding their claims at certain levels. All members benefit when the claims experience is less than estimated by then creating "dividends" or reserve funds to the members, which the members can access and use to offset future premiums and costs if needed.

63. From the employee's perspective, IPBC works very similar to traditional health insurance as the usual carriers provide benefits (generally Blue Cross and Blue Shield of Illinois or United Healthcare, depending on which carrier is selected to be used by the participating member) and it still provides for co-pays, deductibles, and access to the same networks.

64. IPBC engages a third-party provider (Blue Cross or United Healthcare) and a third-party pharmacy benefit manager (Express Scripts) to administer medical benefits claimed under its healthcare benefit programs. Its provider agreements with Blue Cross and United Healthcare limit the covered (*i.e.*, reimbursable) services to those that are "medically necessary." Services and supplies meet this standard if they are "required, in the reasonable medical judgment of the Claim Administrator (*i.e.*, Blue Cross or United Healthcare) for the treatment or management of a medical symptom or condition and that service or care provided is the most efficient and economical service which can be safely provided." IPBC's provider agreement with Express Scripts likewise limits pharmacy benefits to those that are "medically necessary."

65. Thus, like IRMA, IPBC's healthcare plans are obligated to cover all "medically necessary" and "reasonably required" treatment.

66. A treating physician's recommendation for a medically necessary prescription carries great weight in the evaluation of medical necessity carried out by medical management vendors and third-party providers reviewing claims on Plaintiffs' behalf. In prescribing opioids, doctors certify that the treatment is medically necessary and reasonably required, and as such, IRMA's and IPBC's benefits plans authorize payment from their funds on the basis of medical necessity.

67. However, as described below, the use of opioids is not medically necessary or reasonably required to treat chronic pain.

II. Prescription Opioids Are Dangerous Narcotics With No Demonstrated Use For Treating Chronic Non-Cancer Pain.

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

69. 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.[11]

70. 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.

71. 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.[12] There have been

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

[12] *Id.* at 15. 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, M.D., 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-

few randomized controlled trials regarding opioid efficacy for non-cancer pain and even fewer double-blind studies.

72. Critically, while short-term use of opioids for "breakthrough" pain became part of the medical consensus, **no study has found that long-term opioid use is beneficial**.[13]

73. 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. Instead, the Canadian analysis concluded "for functional outcomes the other analgesics were significantly more effective than were opioids."[14]

74. 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*."[15]

75. 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."[16]

76. The 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

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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).

[13] *See* Andrea Rubinstein, *supra* note 12.

[14] 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).

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

[16] 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.

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.[17]

77. One thing is certain about opioids, however: opioid users develop a tolerance for the drug, "typically require[ing] increasingly higher doses in order to maintain the initial level of analgesia—up to 10 times the original dose."[18] 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."[19] 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.[20]

78. Opioid tolerance may begin to develop after a single dose, particularly given the drug's analgesic and euphoric effects.[21]

79. 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

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

[18] 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).

[19] 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.

[20] *Id*.

[21] Nora D. Volkow & A. Thomas McLellan, *supra* note 18;; 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.

drug—a type of Pavlovian conditioning."[22]

80. 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."[23] For instance, opioid users may also seek to increase their dosage and maintain their euphoric high by snorting or injecting crushed opiate pills and tampering with extended release tablets.[24] 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.[25] 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.[26]

81. In 2015, over two million people in the United States had a substance abuse disorder involving prescription opioids.[27]

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[22] Nora D. Volkow & A. Thomas McLellan, *supra* note 18;.

[23] *Id.*; 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/.

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

[25] Nat. Institute on Drug Abuse, *DrugFacts: What is Heroin?* (last revised Jun. 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), https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm.

[26] *See* CDC, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015); *see also* Wilson M. Compton, *supra* note 24.

[27] 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.

82. Because of their potent analgesic and euphoric effects, along with the 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. These prescription opioids are similarly classified as Schedule II narcotics pursuant to the Illinois Controlled Substances Act. 720 ILCS 570/206(b)(1). Schedule II is a category that includes substances like methamphetamine and cocaine.

83. Despite this, "opioids are … frequently prescribed within the [medical] community, where codeine, oxycodone and buprenorphine are commonly used for chronic pain" treatment.[28]

84. 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.[29]

85. Today, the number of opioid prescriptions issued annually in the United States is roughly equal to the size of its entire adult population.[30]

86. Despite the fact that opioids are routinely prescribed, there remains little to no evidence of their safety and efficacy for long-term use. This is true both for chronic pain generally and for specific pain-related conditions.

87. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Instead, research consistently shows

[28] Hasan Pathan & John Williams, *supra* note 11, at 15).

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

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

that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

88. A small number of studies have found that long-term use of opioids can actually make pain worse, a condition known as opioid-induced hyperalgesia.[31]

89. As many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. In one study, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

90. The lack of evidence for the efficacy of opioid use long-term has been well-documented nationally in the context of workers' compensation claims. Long term use of opioids is devastating to return to work.[32] A study of claims by the California Workers Compensation Institute found that workers who received high doses of opioids to treat injuries like back strain stayed out of work three times longer than those with similar injuries who took lower doses.[33]

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[31] *See* Marion Lee, Sanford Silverman, Hans Hansen, Vikram Patel & Laxmaiah Manchikanti, *A Comprehensive Review of Opioid-Induced Hyperalgesia*, Pain Physician Journal, 14: 145-161 (2011), *available at* http://www.painphysicianjournal.com/current/pdf?article=MTQ0Ng%3D%3D&journal=60.

[32] *See* Barry Meier, *Pain Pills Add Cost and Delays to Job Injuries*, N.Y. Times (June 2, 2012), https://www.nytimes.com/2012/06/03/health/painkillers-add-costs-and-delays-to-workplace-injuries.html.

[33] *Id.*; *see also* Alex Swedlow, Laura B. Gardner, John Ireland, & Elizabeth Genovese, *Pain management and the use of opioids in the treatment of back conditions in the California Workers' Compensation System*, California Workers' Compensation Institute (2008), *available at* https://docplayer.net/1743935-Pain-management-and-the-use-of-opioids-in-the-treatment-of-back-conditions-in-the-california-workers-compensation-system.html.

91. A study by the Washington State Department of Labor and Industries found that receiving more than a one-week supply of opioids soon after an injury doubles a worker's risk of disability one year later.[34]

92. Another study found that when prescriptions for certain opioid painkillers were prescribed in workers' compensation injuries, claims were almost four times as likely to have a total cost of $100,000 or more compared with claims without any prescriptions.[35]

93. An annual workers' compensation report from pharmacy benefit managing giant Express Scripts noted: "The issue of opioid prescribing becomes even more important in workers' compensation settings as prolonged opioid use has been shown to be associated with poorer outcomes, longer disability and higher medical costs for injured workers."[36]

94. A recent study by the Workers Compensation Research Institute also points to the adverse effect of longer-term opioid prescriptions on the durations of temporary disability benefits. The study—which used local opioid prescribing patterns to isolate variation in opioids unrelated to characteristics of individual workers, their injuries, and their providers that could affect both opioid prescriptions and return to work—found that these local prescribing patterns exert a strong influence on whether injured workers receive opioid prescriptions, and that workers with longer-term opioid prescriptions had 251 percent longer duration of temporary

[34] Washington State Department of Labor and Industries, Guideline for Prescribing Opioids to Treat Pain in Injured Workers (July 2013), https://lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/FINALOpioidGuideline010713.pdf.

[35] Jeffrey A. White, Xuguang Tao, Milan Talreja, Jack Tower & Edward Bernacki, *The effect of opioid use on workers' compensation claim cost in the State of Michigan*, Journal of Occupational and Environmental Medicine, 54, 948–953 (2012).

[36] 2012 Workers' Compensation Drug Trend Report, Express Scripts (April 2013), *available at* http://lab.express-scripts.com/lab/drug-trend-report/~/media/91453c88e47b42248b8e5c1b30c7ca39.ashx.

disability benefits than workers with no opioid prescriptions. That estimate implies that longer-term opioids more than triple the duration of temporary disability benefits.

95. Since 2002, IRMA has expended tens of millions of dollars on workers' compensation claims involving injured workers who were prescribed opioids for six months or more, including millions on opioid-related medical costs and temporary total disability benefits for injured workers undergoing opioid treatment.

96. As described below, the prevalence (and commercial success) of opioids in general—and certain brands over others—is not the result of the merits of the drugs, but of the aggressive marketing tactics of pharmaceutical industry.

III. Manufacturer Defendants Engaged In A Years-Long Campaign To Change Prescriber Habits And Public Perception Regarding Opioids.

97. 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."[37]

98. This was generally understood even in the early 1990s, when opioids were commonly used to treat acute pain. Before Manufacturer and Front Group Defendants launched the campaign described herein, generally accepted standards of medical practice dictated that opioids should be only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. 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:

[37] Standiford Helm II, et al., *Opioid Epidemic in the United States*, 15 Pain Physician 9 (2012), *available at* https://www.ncbi.nlm.nih.gov/pubmed/22786464?report.

> 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....[38]

99. The market for short-term pain relief is significantly more limited than the market for long-term pain relief. Manufacturer Defendants recognized that if they could sell opioids not just for short term pain relief but also for long-term chronic pain relief, they could achieve blockbuster profits. In order to do so, they knew that they needed to convince doctors and patients that long-term opioid therapy was safe and effective.

100. Manufacturer Defendants knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for patients, health care insurers, and health care payors like Plaintiffs.

101. Nevertheless, in a common scheme (described more fully below), Manufacturer and Front Group Defendants sought to distort medical and public perception of existing scientific data in order to persuade physicians to abandon their long-held apprehensions about prescribing opioids.

102. As outlined below, Manufacturer Defendants' marketing efforts proceeded along two tracks, serving related purposes. First, Manufacturer Defendants worked through third-parties (including Front Group Defendants) to promulgate both branded and unbranded marketing to build confidence in long-term opioid use by overstating its benefits and

[38] 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. 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.

downplaying its risks. In this marketing scheme, Manufacturer Defendants (collectively and individually) poured vast sums of money into generating new literature, creating continuing medical education courses ("CMEs"), creating other "educational" materials, and deploying front groups and key opinion leaders ("KOLs"), all with the intention of creating a new, but false, "consensus" opinion in favor of the long-term use of opioids.

103. Second, Manufacturer Defendants utilized direct marketing tactics to promote their branded opioid products, working 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.

A. Manufacturer Defendants Used "Unbranded" Marketing To Evade Federal Regulations and Consumer Protection Laws.

104. Promotional activity can be branded or unbranded. While branded marketing refers, in this context, to marketing one specific drug (often over another), unbranded marketing refers more generally to material referencing a medical condition or treatment. Drug companies can use unbranded marketing to evade federal regulations governing branded communications.

105. Branded marketing—which identifies and promotes a specific drug—must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[39]

106. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Illinois Food, Drug, and Cosmetic Act, 410 ILCS 620/1 *et seq.*, place further restrictions on branded marketing. The FDCA prohibits the sale in interstate commerce of drugs that are

[39] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

"misbranded."[40] A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[41] "Labeling" includes more than the drug's physical label; it also includes "all ... other written, printed, or graphic matter ... accompanying" the drug, including promotional material. [42]

107. The term "accompanying" is interpreted broadly to include promotional materials - posters, websites, brochures, books, and the like - disseminated by or on behalf of the manufacturer of the drug. Thus, the Manufacturer Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

108. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study."[43] Drug companies further must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[44]

109. Branded promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated. If, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or

[40] 21 U.S.C. § 352(a).

[41] 21 U.S.C. § 352(f); 410 ILCS 620/15.

[42] 21 U.S.C. § 321(k); 410 ILCS 620/2.10.

[43] 21 C.F.R. § 99.101(a)(4).

[44] 21 C.F.R. § 202.1(e)(6)(ii).

making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

110. In order to evade regulatory review, Manufacturer Defendants avoided using branded advertisements to spread their deceptive messages and claims regarding opioids. Instead, Manufacturer Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated unbranded marketing materials—materials that generally promoted opioid use but did not name a specific medication while doing so.

111. 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. By enlisting front groups like Front Group Defendants, drug companies were also able to deceive the public and medical community about the authors of their unbranded marketing materials.

112. Through unbranded materials, Manufacturer Defendants presented information and instructions concerning opioids that were contrary to, or at best inconsistent with, information and instructions listed on Manufacturer Defendants' branded marketing materials and drug labels. This was done with Manufacturer Defendants' knowledge of the true risks, benefits and advantages of opioids. Manufacturer Defendants did so knowingly and in reliance on the fact that such unbranded materials are typically not submitted to nor reviewed by the FDA.

113. Even where such unbranded messages were channeled through Front Group Defendants and other 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. 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 Front Group Defendants and other third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

114. The Front Group Defendants' and other third-parties' publications that 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 Manufacturer 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.

115. As part of a strategic marketing scheme, Manufacturer Defendants spread and validated their deceptive messages through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group Defendants and other patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

1. Manufacturer Defendants used "KOLs".

116. Manufacturer Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Manufacturer Defendants solely because

they favored the aggressive treatment of chronic pain with opioids.[45]

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

118. Pro-opioid doctors have been at the hub of Manufacturer 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 societies that develop, select, and present CMEs.

119. 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.

120. Manufacturer Defendants cited and promoted favorable studies or articles by these KOLs. On the flip side, Manufacturer Defendants did not support, acknowledge, or

[45] 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 the 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.

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.

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

122. Manufacturer Defendants provided substantial opportunities for KOLs to participate in research on topics Manufacturer Defendants suggested or chose, with the predictable effect of ensuring that many studies favorable to opioids 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.

123. 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.

124. 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 below.

125. As indicated above, Dr. Russell Portenoy was a favored 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.

126. Dr. Portenoy was instrumental in opening the door to the use of opioids to treat chronic pain. He served on Defendant American Pain Society ("APS") and Defendant 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.

127. 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 Illinois 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."

128. 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."[46]

129. Dr. Portenoy has also conceded that "[d]ata about the effectiveness of opioids does not exist."[47]

130. To his credit, Dr. Portenoy has recently admitted that he "gave innumerable

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

[47] *Id.*

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.

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 Defendant AAPM, which 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 Manufacturer 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 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."[48]

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 Defendants Purdue, Endo, and Cephalon.

137. Fishman's ties to the opioid drug industry are legion. Fishman was a past president of Defendant AAPM, as well as a board member of the APF, both discussed in more detail below. 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."[49]

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' 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.

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[48] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee J. Sentinel (Feb. 19, 2012), *available at* https://www.medpagetoday.com/neurology/painmanagement/31254.

[49] Scott M. Fishman, *Incomplete Financial Disclosures In A Letter On Reducing Opioid Abuse And Diversion*, 30 J. Am. Med. Ass'n 1445 (2011).

2. 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 Front Group Defendants or other 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 Manufacturer Defendants' departments which 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 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.[50] 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. But Manufacturer Defendants and those acting on their behalf failed 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' 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.

[50] 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' member communities.

149. None of these serious limitations were 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.[51]

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."[52]

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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[51] *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/.

[52] 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.

3. Manufacturer Defendants pushed biased 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.

(a) FSMB Guidelines

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 Manufacturer 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 failed to mention risks of overdose, and discussed addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

157. A 2004 iteration of the FSMB Guidelines also made these claims.

158. A book published in 2007, *Responsible Opioid Prescribing*, was adapted from the 2004 FSMB Guidelines and also made these claims.

159. These guidelines were posted online and were available to and intended to reach physicians that were responsible for deciding whether to prescribe opioids to their patients, including in Illinois and Plaintiffs' networks.

160. 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).

161. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), including in Illinois.[53] The FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale.

162. The FSMB website has described the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."[54] 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

[53] According to the Federation of State Medical Boards, the Illinois Department of Financial and Professional Regulators distributed 500 copies of *Responsible Opioid Prescribing* within Illinois.

[54] The FSMB's current website represents that the book "was developed with the assistance a diverse range of physicians, academicians and health-policy experts and has been used extensively by state regulators and others to address the need for safer, more responsible and better-informed opioid prescribing." "FSMB Foundation Highlights," FSMB, https://www.fsmb.org/fsmb-foundation/foundation-highlights/ (last visited Oct. 10, 2018).

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.

163. Indeed, the FSMB actually issued a report calling on medical boards to punish doctors who inadequately treat pain.[55]

164. 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 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.

165. 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*.

166. 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.[56]

(b) AAPM/APS Guidelines

167. Similarly flawed guidelines were published by Defendants AAPM and APS, each of which received substantial funding from Manufacturer Defendants. These organizations

[55] Thomas Catan & Evan Perez, *supra* note 46.

[56] 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.

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.

168. The co-author of the AAPM-APS statement, KOL Dr. David Haddox, was at the time a paid speaker for Purdue.[57] 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 that were responsible for deciding whether to prescribe opioids to their patients, including in Illinois and Plaintiffs' networks.

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

170. 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.

171. The Institute of Medicine recommends that, to ensure an unbiased result, fewer

[57] 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.

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.

172. The AAPM-APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians in Plaintiffs' networks, but also the body of scientific evidence on opioids. The Guidelines have been cited 732 times in academic literature, are still available online, and were even reprinted in the Journal of Pain.

173. Manufacturer Defendants widely referenced and promoted the 2009 AAPM-APS Guidelines without disclosing the acknowledged lack of evidence to support them.

(c) American Geriatrics Society

174. Finally, Defendant 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*) and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*). *Pharmacological Management of Persistent Pain in Older Persons* 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."[58]

175. 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.

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

176. AGS contracted with Manufacturer Defendants Endo, Purdue, and Janssen to disseminate *Pharmacological Management of Persistent Pain in Older Persons*, and to sponsor CMEs based on them. These Manufacturer Defendants were aware of the content of *Pharmacological Management of Persistent Pain in Older Persons* when they agreed to provide funding for these projects. *Pharmacological Management of Persistent Pain in Older Persons* was released at the May 2009 AGS Annual Scientific Meeting in Chicago and first published online on July 2, 2009. AGS submitted grant requests to Manufacturer Defendants including Endo and Purdue beginning July 15, 2009.

177. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[59] 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.

(d) Guidelines That Did Not Receive Manufacturer Defendants' Support

178. The extent of Manufacturer Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines—the authors of which did not accept drug company funding—reached very different conclusions.

179. For example, the 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of

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

these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advised that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommended long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[60]

180. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommended against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.[61]

181. *The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD")

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[60] Laxmaiah Manchikanti, et al., *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment, 15 Pain Physician (Special Issue) S1-S66; Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

[61] American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids, (2011), *available at* https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf.

in 2010, noted that its review:

> revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps ... include: lack of effectiveness studies on long-term benefits and harms of opioids....; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification....; lack of evidence on the utility of informed consent and opioid management plans....; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.[62]

4. Manufacturer Defendants relied on Continuing Medical Education programs.

182. 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.

183. 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.

184. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, 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 Defendants' deceptions (delivered via KOLs).

185. In all, Manufacturer Defendants sponsored CMEs that were delivered thousands

[62] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010), *available at* https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf.

of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

186. 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."[63]

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

188. 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

[63] Opinion 9.2.7, *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.

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.[64]

189. By sponsoring CME programs put on by Front Group Defendants like APF and AAPM, and other front groups (as described below), 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.

5. Manufacturer Defendants made use of Front Group Defendants.

190. 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 Manufacturer 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 Manufacturer 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 Manufacturer Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain.

191. Manufacturer Defendants funded these front groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

192. Front Group Defendants APS, AGS, and AAPM are such front groups, and there

[64] Letter from Senator Claire McCaskill to James A. Schoeneck, President and Chief Executive Officer of Depomed, at 2–3 (Mar. 28, 2017) *available at* https://www.hsgac.senate.gov/imo/media/doc/McCaskill%20Opioid%20Letters.pdf.

are others including the FSMB, the American Chronic Pain Association ("ACPA"), and the American Society of Pain Educators ("ASPE"), as shown in Figure 1 below.

	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: Financial Ties Between Defendants and front groups.[65]

[65] U.S. Senate Homeland Security & Governmental Affairs Comm, *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.

(a) American Pain Foundation.

193. For years, the most prominent of the 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 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.

194. 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 to and reached national audiences.

195. 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 Manufacturer 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."

196. In practice, APF operated in extremely close collaboration with opioid

manufacturers. 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.

197. 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.

198. *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.)

199. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose that opioids may cause fatal interactions with benzodiazepines, 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, as further discussed below. 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.

200. *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*.

201. 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 Manufacturer Defendants stopped funding it.

202. 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."

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 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 Manufacturer 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, Manufacturer 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.

(b) The American Academy of Pain Medicine.

207. Defendant AAPM is similarly conflicted. Since 2009, AAPM has received over $2.2 million in funding from opioid manufacturers. Its board members, staff members, and other executives have likewise received payments from opioid makers; Dr. Charles Argoff, president of AAPM, received more than $600,000 from opioid manufacturers between 2013 and 2016.[66]

208. AAPM maintains a corporate relations council, whose members pay $25,000 per

[66] U.S. Senate Homeland Security & Governmental Affairs Comm., Ranking Member's Office, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, *available at* https://bloximages.newyork1.vip.townnews.com/stltoday.com/content/tncms/assets/v3/editorial/4/b7/4b729458-58c5-50ba-a934-e0ed9f7c424d/5a82ed4815d51.pdf.pdf.

year (on top of other funding) to participate. The benefits include 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.

209. 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.

210. 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."[67]

211. 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.

(c) The American Pain Society.

212. Defendant APS played a prominent role in changing the way doctors think about

[67] 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.*

pain (and the market for pain management) by advocating for doctors to elevate pain to the "fifth vital sign," along with temperature, pulse, breathing rate, and blood pressure.

213. The concept was introduced at APS's 1996 annual conference in Los Angeles, when James Campbell, a neurosurgeon at Johns Hopkins University and then-president of APS, delivered the keynote address arguing for the need "to train doctors and nurses to treat pain as a vital sign."[68] The speech resonated.[69]

214. APS went on to trademark the slogan "Pain: The Fifth Vital Sign." Campbell went on to help found APF, which received generous funding from Purdue.

215. Shortly thereafter, the Veteran's Health Administration included pain as "the 5th vital sign" in their national pain-management strategy. In November 1998, the Veterans Health Administration sent a memo to its 1,200 clinics requiring clinicians to ask patients about their pain level at each visit.[70]

216. Two years later, the Joint Commission on Accreditation of Healthcare Organizations released its *Standards Related to the Assessment and Treatment of Pain* and began surveying hospitals in 2001 for compliance with the standards. The Joint Commission's standards highlighted the need to regularly ask and assess pain of hospitalized patients, ushering in the daily use of pain scales. (The Joint Commission also published a guide—incidentally sponsored by Purdue— explaining that some healthcare providers have "inaccurate and exaggerated concerns" regarding addiction, tolerance, and the risk of death.)

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[68] J.N. Campbell, *American Pain Society (APS) 1995 presidential address*, Pain Forum, 5, 85–8 (1996).

[69] *See, e.g.,* N.E. Morone & D.K. Weiner, *Pain as the 5th vital sign: Exposing the vital need for pain education*, Clinical Therapeutics, 35(11), 1728-1732 (2013).

[70] Veterans Health Administration, *Pain: The 5th vital sign*, Department of Veterans Affairs (2000).

217. During the time that Campbell served as president for the APS, the society received funding from Purdue, the manufacturer of OxyContin, which at the same time debuted on the United States drug market to blockbuster sales. Later in 2007, Campbell testified before the Senate Judiciary Committee defending Purdue's role in increased incidence of abuse of OxyContin, claiming that "the scientific evidence suggests that addiction to opioids by legitimate chronic pain patients without prior histories of substance abuse using the medication as directed is rare."[71]

218. Between January 2012 and March 2017, APS received $962,725 in funding from opioid manufacturers, including Defendants Purdue and Janssen.

219. Like the cigarette manufacturers that 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, Front Group Defendants and the other 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, who were deceived into believing the false claims.

B. Manufacturer Defendants Promoted Their Branded Products Through Direct Marketing To Prescribers And Customers.

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

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[71] Statement of Dr. James N. Campbell, Hearing on "Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement" before the United States Senate Committee on the Judiciary (July 31, 2007), *available at* https://www.judiciary.senate.gov/imo/media/doc/Campbell%20Testimony%20073107.pdf.

1. Manufacturer Defendants relied upon branded published advertisements

221. Manufacturer Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists (such as the Journal of Pain and Clinical Journal of Pain) to journals with wider medical audiences (such as the Journal of the American Medical Association). Manufacturing 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. The total number and rate of opioid prescriptions dispensed in the United States peaked in 2012.

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

2. Manufacturer Defendants relied upon sales representatives and self-recruited physician speakers.

223. 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.

224. 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.

225. 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.[72]

226. 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 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.

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

228. 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.

229. Manufacturer Defendants' sales representatives have visited hundreds of thousands of doctors. 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.

230. Each Manufacturer Defendant carefully trained its sales representatives to deliver

[72] *See, e.g.,* Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 Mktg. Letters 129 (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, *supra* note 3 (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).

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 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 that have been 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).

231. 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.

232. 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.

233. Pharmaceutical companies 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.

234. These speaker programs and associated speaker training serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, opioids; they 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.

235. Manufacturer Defendants graded their speakers, and future opportunities were based on speaking performance, post-program sales, and product usage. Manufacturer

Defendants also tracked the prescribing of event attendees.

236. Like the sales representatives who select them, speakers are expected to stay "on message"—indeed, they agreed in writing to follow the slide decks provided to them by Manufacturer Defendants. Speakers thus gave the appearance of providing independent, unbiased presentations on opioids, when in fact they were presenting a script prepared by Manufacturer Defendants.

237. 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 afforded Manufacturer Defendants greater freedom in the messages they could convey to doctors.

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

239. The total figure is more than double Manufacturer Defendants' collective spending on detailing in 2000.

C. Manufacturer Defendants' Marketing Messages Were Misleading And Unfair.

240. Manufacturer Defendants' marketing of opioids for long-term use to treat chronic pain, both branded and unbranded, directly and with and through third parties, included information that was false, misleading, contrary to credible scientific evidence and their own labels, and lacked balance and substantiation. Their marketing materials omitted material information about the risks of opioids, and overstated their benefits. Moreover, Manufacturer

Defendants inaccurately suggested that chronic opioid therapy was supported by evidence, and failed to disclose the lack of evidence in support of treating chronic pain with opioids.

241. There are seven primary misleading and unfounded representations that have been disseminated by Manufacturer Defendants in the manners described above.[73] Defendants have both individually and collectively:

- 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.

242. 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.

D. The U.S. Senate Investigated—And Confirmed—Manufacturer Defendants' Deceptive And Unfair Practices.

[73] *See, e.g.*, Patrick Radden Keefe, *supra* note 57; 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) https://www.nbcnews.com/storyline/americas-heroin-epidemic/many-doctors-get-goodies-opioid-makers-n791281 (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.")

243. 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.

244. The Senate Finance Committee sent letters to 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).

245. 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.[74]

246. 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.[75]

247. 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 – comprises about five percent of the world population, but we use about two-thirds of the world supply of opioids.[76]

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[74] 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.

[75] 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/.

[76] *WATCH: McCaskill Leads Roundtable On Role of Drug Manufacturers In The Opioid Crisis*,

248. 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.

249. 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 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."

E. Each Manufacturer Defendant Engaged In Deceptive Marketing, Both

PBS (Sept. 12, 2017), https://www.pbs.org/newshour/health/watch-live-mccaskill-leads-roundtable-role-drug-manufacturers-opioid-crisis.

Directly and Through Third Parties, That Targeted And Reached Prescribers In Plaintiffs' Network.

250. 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).

251. This conduct was a part of a unified plan, and was engaged in individually by each Defendant. Representative examples of their conduct follow:

1. Purdue.

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

253. Purdue, which is privately held by the Sackler family, manufactures, and then markets, sells, and distributes the following Schedule II narcotics nationwide:

- **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.[77]

254. 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).

255. 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.

256. Purdue engaged in in-person marketing to doctors in Illinois and operated speakers bureau programs that included and targeted Illinois prescribers. Purdue had 250 sales representatives in 2007, of whom 150 were devoted to promoting sales of OxyContin full time. Like the other Defendants' detailers, Purdue sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed, identically, across the country. These sales representatives were critical in delivering Purdue's marketing strategies and talking points to individual prescribers.[78]

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[77] 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.

[78] But Purdue did not stop there. It also tracked around 1,800 doctors whose prescribing patterns demonstrated a probability that they were writing opioid prescriptions for addicts and drug dealers. Purdue kept the program secret for nine years and, when it finally did report information

257. Purdue's sales culture, including in Plaintiffs' member 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."

258. 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.

259. 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's Deceptive Direct Marketing,

(i) *Purdue falsely marketed extended-release OxyContin as superior to immediate-release opioids and downplayed the risks of addiction.*

260. Purdue launched OxyContin 20 years ago with a powerful, bold claim: "One dose relieves pain for 12 hours, more than twice as long as generic medications."[79] Purdue told doctors in its OxyContin press release that a single tablet would provide "smooth and sustained pain control all day and all night."

261. Purdue knew, however, that these claims were misleading because, for many

about these suspicious doctors to law enforcement authorities, it only did so with respect to 8% of them.

[79] 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/.

patients, the pain relief lasted for as little as eight hours, which led to end-of-dose failure and withdrawal symptoms and prompted doctors to prescribe or patients to take higher or more frequent doses of opioids, all of which increased the risk of abuse and addiction.

262. For example, a "Conversion and Titration Guide" submitted to the FDA and distributed to physicians by Purdue, prominently referred to "Q12h OxyContin Tablets," meaning that each tablet is intended to "offer your patient every-twelve-hour dosing." Other marketing materials directed at physicians and disseminated across the country in 2006 touted that OxyContin's "12-hour AcroContin Delivery System" is "designed to deliver oxycodone over 12 hours," which offered patients "life with Q12H relief." Those same marketing materials included a timeline graphic with little white paper pill cups only at "8AM" and, further down the line, at "8PM." They also proclaimed that OxyContin provides "Consistent Plasma Levels Over 12 Hours" and set forth charts demonstrating absorption measured on a logarithmic scale, which fraudulently made it appear levels of oxycodone in the bloodstream slowly taper over a 12-hour time period.

263. Purdue advertisements that ran in 2005 and 2006 issues of the Journal of Pain depict a sample prescription for OxyContin with "Q12h" handwritten. Another advertisement Purdue ran in 2005 in the Journal of Pain touted OxyContin's "Q12h dosing convenience" and displayed two paper dosing cups, one labeled "8 am" and one labeled "8 pm," implying that OxyContin is effective for the 12-hour period between 8 a.m. and 8 p.m. Similar ads appeared in the March 2005 Clinical Journal of Pain.

264. Further, to this day, Purdue includes prominent 12-hour dosing instructions in its branded advertising, such as in a 2012 Conversion and Titration Guide, which states: "Because each patient's treatment is personal / Individualize the dose / Q12h OxyContin Tablets."

265. Purdue's direct marketing materials also misrepresented that opioids would help patients regain functionality and make it easier for them to conduct everyday tasks like walking, working, and exercising.

266. For example, in 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted over a span of several months. One such patient, "Paul," is described to be a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth—that there is no evidence that opioids improve patients' lives and ability to function (and there was substantial evidence to the contrary).

267. 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.

268. 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.

269. 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.

270. 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.

271. 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.

272. 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."[80]

273. 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.

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

> 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.

274. 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.

275. 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 OxyContin 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

- 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.[81]

276. 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."[82]

277. 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 of the total prescription opioid market.83Rather than target physicians prescribing opioids for understood, scientifically-supported uses, Purdue heavily promoted OxyContin 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.[84]

278. Purdue sales representatives 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

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

[82] 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.

[83] 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.

[84] Barry Meier, *supra* note 82.

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.[85]

279. In 2011, Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs—and therefore the prevalence—of addiction. However, Purdue knew that OxyContin was used non-medically by injection less than less than 17% of the time. Yet, *Providing Relief, Preventing Abuse* prominently listed side effects of injection like skin popping and track marks as "Indications of Possible Drug Abuse"—downplaying much more prevalent signs of addiction associated with OxyContin use, such as asking for early refills, and making it seem that addiction only occurs when opioids are taken illicitly.

280. *Providing Relief, Preventing Abuse* also deceptively camouflaged the risk of addiction by falsely supporting the idea that drug-seeking behavior could, in fact, be a sign of "pseudoaddiction" rather than addiction itself. Specifically, it noted that the concept of pseudoaddiction had "emerged in the literature" to describe "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." Nowhere in Providing Relief, Preventing Abuse did Purdue disclose the lack of scientific evidence justifying the concept of pseudoaddiction, nor that it was coined by a Purdue vice president.

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

282. Purdue tracked physicians' prescribing practices by reviewing pharmacy

[85] Art Van Zee, *supra* note 3.

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.[86]

283. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from its sales representatives, and, in some cases, its own investigations.87 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.

284. According 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."[88]

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[86] 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 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/local/la-me-oxycontin-drug-ring-part-2-20160710-story.html.

[87] 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.

[88] Harriet Ryan, et al., *supra* note 86.

(ii) *Purdue used unbranded marketing to downplay the risks of addiction.*

285. Purdue also disseminated misrepresentations through two of its unbranded websites, *In the Face of Pain* and *Partners Against Pain*.

286. Consistent with Purdue's efforts to portray opioid treatment as "essential" for the proper treatment of chronic pain and label skepticism related to chronic opioid therapy as an "inadequate understanding" that leads to "inadequate pain control," In the Face of Pain criticized policies that limited access to opioids as being "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. This was meant to imply that patients should keep looking until they find a doctor willing to prescribe opioids.

287. Purdue also used its unbranded website *Partners Against Pain* to promote the deceptive messages regarding risk of addiction that were delivered by its sales representatives. On this website, Purdue posted Clinical Issues in Opioid Prescribing, a pamphlet that was copyrighted in 2005. Purdue distributed a hard-copy version of this pamphlet at least as of November 2006. Clinical Issues in Opioid Prescribing claimed that "illicit drug use and deception" were not indicia of addiction, but rather indications that a patient's pain was undertreated. The publication indicated that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated." In other words, Purdue suggested that when faced with drug-seeking behavior from their patients, doctors should prescribe more opioids—turning evidence of addiction into an excuse to sell and prescribe even more drugs.

(b) Purdue's Deceptive Third-Party Statements.

288. Purdue's false marketing scheme did not end with its own sales representatives

and branded marketing materials; it also engaged third parties (including Front Group APF) to spread the false message of their prescription opioids' safety and efficacy.

(i) *Purdue's Control of APF.*

289. Purdue exercised considerable control over APF, which published and disseminated in many of the most blatant falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, is described in detail below.

290. Purdue exercised its dominance over APF over many projects and years. Purdue was APF's second-biggest donor, with donations totaling $1.7 million. Purdue informed APF that the grant money reflected Purdue's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," making clear that Purdue's funding depended upon APF continuing to support Purdue's business interests. Indeed, Purdue personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, Purdue suggested what role APF could play that would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups that, upon information and belief, APF reached out to. Purdue personnel remained in constant contact with their counterparts at APF.

291. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's

periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

292. Purdue used this agreement to conduct work with APF on the *Partners Against Pain* website. *Partners Against Pain* is a Purdue-branded site, and Purdue holds the copyright. However, its ability to deploy APF on this project illustrates the degree of control Purdue exercised over APF. In 2011, it hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson. Purdue contemplated paying this consultant $7,500 in fees and expenses for 26 hours of work. Purdue would require this consultant to "to discuss and rehearse the delivery of [Purdue's] campaign messages" and Purdue committed that "[m]essage points will be provided to [the] Consultant in advance and discussed on [a planned] call." At all times, decisions regarding the final content on the *Partners Against Pain* website were "at the sole discretion of Purdue."

293. APF also volunteered to supply one of its staff (a medical doctor or a nurse practitioner) to assist Purdue as a consultant and spokesperson in connection with the launch of one of Purdue's opioid-related projects, Understanding & Coping with Lower Back Pain, which appeared on *Partners Against Pain*. One of the consultants was APF's paid employee, Mickie

Brown. The consultant's services would be provided in return for a $10,000 in consulting fees for APF and $1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances would be reviewed and approved by individuals working for Purdue. Purdue initiated this project, and it was not until later that APF worried about "how Purdue sees this program fitting in with our [existing] grant request."

294. Given the financial and reputational incentives associated with assisting Purdue in this project and the direct contractual relationship and editorial oversight, APF personnel were acting under Purdue's control at all relevant times with respect to *Partners Against Pain*.

295. Purdue often asked APF to provide "patient representatives" for Partners Against Pain, and APF fulfilled these requests. Moreover, APF staff and board members and front groups ACPA and AAPM, among others (such as Dr. Webster), appear on Inthefaceofpain.com as "Voices of Hope"—"champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. APF also contracted with Purdue for a project on back pain where, among other things, it provided a patient representative who agreed to attend a Purdue-run "media training session."

296. According to an Assurance of Voluntary Compliance ("AVC") entered into between the New York Attorney General and Purdue Pharma on August 19, 2015, Inthefaceofpain.com received 251,648 page views between March 2014 and March 2015. Except in one document linked to the website, Inthefaceofpain.com makes no mention of opioid abuse or addiction. Purdue's copyright appears at the bottom of each page of the website, indicating its ownership and control of its content. There is no other indication that 11 of the individuals who provided testimonials on Inthefaceofpain.com received payments, according to the AVC, of $231,000 for their participation in speakers' programs, advisory meetings and travel costs

between 2008 and 2013. Therefore, the New York Attorney General found Purdue's failure to disclose its financial connections with these individuals had the potential to mislead consumers by failing to disclose the potential bias of these individuals.

297. Nowhere was Purdue's influence over APF so pronounced as it was with the APF's "Pain Care Forum" ("PCF"). Based on interviews conducted and documents reviewed by the City, PCF was and continues to be run not by APF, but by Defendant Purdue's in-house lobbyist, Burt Rosen. As described by a former drug company employee, Burt Rosen was able to tell PCF "what to do and how to do it," and also asserted that this allowed him to run APF. According to this employee, to Rosen's thinking, "PCF was APF, which was Purdue." The group meets regularly in-person and via teleconference and shares information through an email listserv.

298. In 2011, APF and another third-party advocacy group, the Center for Practical Bioethics, were contemplating working together on a project. Having reviewed a draft document provided by the Center for Practical Bioethics, the APF employee cautioned that "this effort will be in cooperation with the efforts of the PCF" and acknowledged that "I know you have reservations about the PCF and pharma involvement, but I do believe working with them and keeping the lines of communications open is important." The Center for Practical Bioethics CEO responded by indicating some confusion about whom to speak with, asking "[i]s Burt Rosen the official leader" and reflecting what other sources have confirmed.

299. In 2007, the PCF Education Subgroup, consisting of drug companies Purdue and Alpharma, and front groups APF and ACPA (self-described as "industry-funded" groups), developed a plan to address a perceived "lack of coordination" among the industry and pro-opioid professional and patient organizations. PCF members agreed to develop simplified "key"

messages" to use for public education purposes. Their messages were reflected in programs like NIPC's *Let's Talk Pain* (put together by Endo and APF), and Purdue's *In the Face of Pain*.

300. When the FDA required drug companies to fund CMEs related to opioid risks in connection with its 2009 REMS, Purdue, along with these front groups, worked through the PCF to ensure that, although it was mandatory for drug companies to fund these CMEs, it would not be mandatory for prescribers to attend them. A survey was circulated among Defendants Endo, Janssen, and Purdue, which predicted that the rates of doctors who would prescribe opioids for chronic pain would fall by 13% if more than four hours of mandatory patient education were required in connection with the REMS. With a push from PCF, acting under Purdue's direction, they were not.

301. APF showed its indebtedness to Purdue and its willingness to serve its corporate agenda by testifying on the company's behalf at a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the OxyContin criminal settlement."[89] Despite its ostensible role as a patient advocacy organization, APF was willing to overlook substantial evidence—resulting in the jailing of Purdue executives—that Purdue blatantly, and despite its clear knowledge to the contrary, told physicians and patients that OxyContin was "rarely" addictive and less addictive than other opioids. Like Purdue and despite the leadership of numerous medical doctors and researchers on its board, APF ignored the truth about opioids

[89] Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Before the S. Comm. On the Judiciary, 110th Cong. 46-50, 110-116 (2007) (statements of Dr. James Campbell, Chairman, APF). Purdue also was able to exert control over APF through its relationships with APF's leadership. Purdue-sponsored KOLs Russell Portenoy and Scott Fishman chaired APF's board. Another APF board member, Perry Fine, also received consulting fees from Purdue. APF board member Lisa Weiss was an employee of a public relations firm that worked for both Purdue and APF. Weiss, in her dual capacity, helped vet the content of the Purdue-sponsored Policymaker's Guide, which is described below.

and parroted Purdue's deceptive messaging. Purdue testified on Purdue's behalf that addiction was a "rare problem" for chronic pain patients and asserted: "[T]he scientific evidence suggests that addiction to opioids prescribed by legitimate chronic non-cancer pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of OxyContin and the abuse and diversion of the drug." There was, and is, no scientific support for those statements.

302. APF President Will Rowe reached out to Defendants—including Purdue—rather than his own staff to identify potential authors to draft an answer to an article critical of opioids that appeared in the Archives of Internal Medicine in 2011.

303. Purdue's control over APF shaped and was demonstrated by specific APF, pro-opioid publications. These publications had no basis in science and were driven (and can only be explained) by the commercial interest of pharmaceutical companies—Purdue chief among them.

(a) *A Policymaker's Guide*

304. Purdue provided significant funding to and was involved with APF in creating and disseminating *A Policymaker's Guide to Understanding Pain & Its Management* ("*Policymaker's Guide*"), which was originally published in 2011. *Policymaker's Guide* misrepresented that that there were studies showing that the use of opioids for the long-term treatment of chronic pain could improve patients' ability to function.

305. Specifically, *Policymaker's Guide* claimed that "multiple clinical studies" demonstrated that "opioids . . . are effective in improving [d]aily function, [p]sychological health [and] [o]verall health-related quality of life for people with chronic pain" and implied that these studies established that the use of opioids long-term led to functional improvement. The study cited in support of this claim specifically noted that there were no studies demonstrating the

safety of opioids long-term and noted that "[f]or functional outcomes, the other [studied] analgesics were significantly more effective than were opioids."90

306. *Policymaker's Guide* also misrepresented the risk of addiction. It claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and that "less than 1% of children treated with opioids become addicted."

307. Moreover, *Policymaker's Guide* attempted to distract doctors from their patients' drug-seeking behavior by labeling it as pseudoaddiction, which, according to the guide, "describes patient behaviors that may occur when pain is undertreated." Like Partners Against Pain, Policymaker's Guide noted that "[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." The similarity between these messages regarding pseudo-addiction highlights the common, concerted effort behind Purdue's deceptive statements.

308. *Policymaker's Guide* further misrepresented the safety of increasing doses of opioids and deceptively minimized the risk of withdrawal. For example, Policymaker's Guide claimed that "[s]ymptoms of physical dependence" on opioids in long-term patients "can often be ameliorated by gradually decreasing the dose of medication during discontinuation" while omitting the significant hardship that often accompanies cessation of use. Similarly, *Policymaker's Guide* taught that even indefinite dose escalations are "sometimes necessary" to reach adequate levels of pain relief, but it completely omitted the safety risks associated with increased doses.

309. Purdue provided substantial assistance toward the creation and dissemination of *Policymaker's Guide*, which APF ultimately disseminated on behalf of Defendants, including

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[90] Andrea D. Furlan et al., *supra* note 14.

Purdue. Purdue provided $26,000 in grant money to fund the development and dissemination of its content. Purdue kept abreast of the content of the guide as it was being developed, and, based on the periodic reports APF provided to Purdue regarding its progress on *Policymaker's Guide*, had editorial input into its contents.

310. *Policymaker's Guide* was posted online, and was available to and intended to reach Illinois prescribers and consumers.

(b) *Treatment Options: A Guide for People Living with Pain.*

311. Purdue's partnership with APF did not end with *Policymaker's Guide*. Purdue also substantially assisted APF by sponsoring *Treatment Options: A Guide for People Living with Pain* ("*Treatment Options*"), starting in 2007. Based on Purdue's control of other APF projects, Purdue also would have exercised control over Treatment Options.

312. *Treatment Options* is rife with misrepresentations regarding the safety and efficacy of opioids. For example, *Treatment Options* misrepresented that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids "give [pain patients] a quality of life [they] deserve."

313. Further, as outlined above, *Treatment Options* claimed that addiction is rare and, when it does occur, involves unauthorized dose escalations, patients who receive opioids from multiple doctors, or theft, which paints a narrow and misleading portrait of opioid addiction. As described above, there is no scientific evidence corroborating that statement, and such statements are, in fact, false because available data demonstrates that patients on chronic opioid therapy are less likely to participate in life activities like work.

314. *Treatment Options* also promoted the use of opioids to treat long-term chronic pain by denigrating alternate treatments, most particularly NSAIDs. *Treatment Options* noted

that NSAIDs can be dangerous at high doses and inflated the number of deaths associated with NSAID use, and distinguished opioids as having less risk. According to *Treatment Options*, NSAIDs were different from opioids because opioids had "no ceiling dose," which was beneficial since some patients "need" larger doses of painkillers than they are currently prescribed. *Treatment Options* warned that the risks associated with NSAID use increased if NSAIDs were "taken for more than a period of months," but deceptively omitted any similar warning about the risks associated with the long-term use of opioids.

315. APF distributed 17,200 copies of *Treatment Options* in 2007 alone. *Treatment Options* was also posted online. It was available to and intended to reach Illinois prescribers and patients.

(c) *Exit Wounds.*

316. Purdue also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

317. Purdue provided APF with substantial assistance in distributing *Exit Wounds* in Illinois and throughout the nation by providing grant money and other resources.

(ii) *Purdue's Work With Other Third Party Front Groups and KOLs.*

318. Purdue also provided other third-party front groups with substantial assistance in issuing misleading statements regarding the risks, benefits, and superiority of opioids for the long-term treatment of chronic pain.

(a) FSMB—*Responsible Opioid Prescribing.*

319. In 2007, Purdue sponsored FSMB's *Responsible Opioid Prescribing*, which deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

Responsible Opioid Prescribing also was drafted by "Medical Writer X."

320. Purdue spent $150,000 to help FSMB distribute *Responsible Opioid Prescribing.* The book was distributed nationally, and its message was available to and intended to reach prescribers in Plaintiffs' network.

(b) AGS—*Pharmacological Management of Persistent Pain in Older Persons,*

321. Purdue worked with the AGS on a CME to promote the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. As discussed above in Section A.3.c., these guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse" when the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain should be considered for opioid therapy (low quality of evidence, strong recommendation)."

322. Controversy surrounding earlier versions of AGS guidelines had taught AGS that accepting money directly from drug companies to fund the guidelines' development could lead to allegations of bias and "the appearance of conflict." Accordingly, AGS endeavored to eliminate "the root cause of that flack" by turning down commercial support to produce the 2009 Guidelines. Having determined that its veneer of independence would be tarnished if it accepted drug company money to create the content, AGS decided to develop the guidelines itself and turn to the drug companies instead for funding to distribute the pro-drug company content once it had been created. As explained by AGS personnel, it was AGS's "strategy that we will take commercial support to disseminate [the 2009 Guidelines] if such support is forthcoming." AGS knew that it would be difficult to find such support unless the report was viewed favorably by opioid makers.

323. AGS sought and obtained grants from Purdue to distribute *Pharmacological Management of Persistent Pain in Older Persons.* As a result, the publication was distributed nationally, and its message was available to and was intended to reach prescribers in Plaintiffs' network.[91]

(iii) *CME's.*

324. Purdue sponsored a 2012 CME program taught by Steven Stanos, a Chicago-based KOL, called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids. This CME was presented at various locations in the United States.

325. Purdue also sponsored a 2011 CME taught by KOL Lynn Webster via webinar titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation likewise deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." At the time, Dr. Webster was receiving significant funding from Purdue. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Purdue (and other Defendants). The webinar was available to and was intended to reach prescribers nationwide.

326. Purdue also sponsored a CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse. Path of the Patient is devoted entirely to

[91] As described above, Purdue also provided substantial support for the AAPM/APS guidelines. The 1997 AAPM and APS consensus statement *The Use of Opioids for the Treatment of Chronic Pain* was authored by one of its paid speakers, and 14 out of 21 panel members who drafted the AAPM/APS Guidelines received support from Defendants Janssen, Cephalon, Endo, and Purdue.

treating chronic pain with opioids. Although the program purports to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it does no such thing. This "educational" program, addressing treatment of a population known to be particularly susceptible to opioid addiction, presents none of the alternative treatment options available, but only discusses treatment of chronic pain with opioids.

327. In a role-play in Path of the Patient, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Despite these facts, the narrator notes that, because of a condition known as "pseudoaddiction," the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role play treats this patient by prescribing a high-dose, long-acting opioid. This CME was available online and was intended to reach prescribers nationwide.

328. Purdue also sponsored a CME titled Overview of Management Options and issued by the American Medical Association in 2003, 2007, and 2013 (the latter of which was still available for CME credit as of June 2018). The CME was edited by KOL Russel Portenoy, among others. It deceptively instructed physicians that NSAIDs and other drugs, but not opioids, are unsafe at high doses. In fact, the data indicates that patients on high doses of opioids are more likely to experience adverse outcomes than patients on lower doses of the drugs. Dr. Portenoy received research support, consulting fees, and honoraria from Purdue (among others), and was a paid Purdue consultant. This CME was presented online intended to reach prescribers nationwide.

(iv) *Purdue's Misleading Science.*

329. Purdue also misrepresented the risks associated with long-term opioid use by promoting scientific studies in a deceptive way. In 1998, Purdue funded two articles by Dr. Lawrence Robbins in Chicago, which showed that between 8% and 13% of the patients he studied became addicted to opioids—a troubling statistic for Purdue, whose market, and marketing, depended upon the claim that opioids were rarely addictive.[92] Purdue had these articles placed in headache-specific journals, where they would be less likely to be encountered by pain specialists or general practitioners. The first of these articles has been cited a mere 16 times; the second does not even appear on Google scholar. Five years later, Purdue also funded a study of OxyContin in diabetic neuropathy patients, which was published in 2003. Notwithstanding that Purdue-funded studies, testing Purdue's own drugs, had previously indicated that addiction rates were between 8% and 13%, Purdue's 2003 article reached back to the 1980 Porter-Jick Letter to support its claim that OxyContin was not commonly addictive. This article was placed in a prominent pain journal and has been cited 487 times.[93] While this article was drafted over a decade ago, it continues to be relied upon to further the misrepresentations that opioids are not addictive.

2. Cephalon.

330. Cephalon manufactures, and then markets, sells and distributes the following

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

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

Schedule II opioids nationwide, including in Plaintiffs' member communities:

- **Actiq (fentanyl citrate)**. An opioid analgesic and oral lozenge containing fentanyl citrate, which is 80 times more potent than morphine.[94] 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.

331. 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."[95]

332. 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 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."[96] 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.[97]

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

[95] FDA Approval Letter for NDA 20-747 (Nov. 4, 1998) at 5, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.

[96] Actiq Drug Label, July 2011. The 1998 version does not substantively differ: "Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, Actiq is contra-indicated in the management of acute or postoperative pain. This product must not be used in opioid non-tolerant patients." (Emphasis in original).

[97] John Carreyrou, *supra* note 95.

333. In October 2000, Cephalon acquired the worldwide rights to Actiq and began 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's Deceptive Direct Marketing.

(i) *Cephalon aggressively markets a cancer pain drug to physicians who do not treat cancer.*

334. 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' member communities.

335. According to "[d]ata gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits to non-oncologists to pitch Actiq increased 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.[98]

336. 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.[99]

337. 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."[100]

(ii) *Cephalon is found to have falsely marketed Actiq for off-label uses.*

338. 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, 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).

339. According to a Department of Justice press release, Cephalon trained sales

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[98] John Carreyrou, *supra* note 95.

[99] John Carreyrou, *Narcotic supra* note 95; Cephalon, Inc. Annual Report (Form 10-K), at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.

[100] John Carreyrou, *supra* note 95.

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.[101]

340. Upon information and belief, the government's investigation uncovered documents confirming that Cephalon directly targeted non-oncology practices and pushed its sales representatives 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-label uses, such as treating migraine headaches and for non-opioid-tolerant patients.[102]

341. Yet this had little, if any, impact on Cephalon. It continued with its deceptive

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[101] 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

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

marketing strategy for Actiq and Fentora in the years to come.

(iii) *Cephalon fraudulently markets Actiq's successor drug, Fentora.*

342. Actiq was set to lose its patent protection in September 2006. To replace the revenue stream that would be lost once generic competitors came to market, Cephalon purchased a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application ("NDA") to the FDA for approval.

343. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Fentora's unusually strong and detailed black box warning label—the most serious medication warning required by the FDA—makes clear that, among other things:

> Fatal respiratory depression has occurred in patients treated with FENTORA, including following use in opioid non-tolerant patients and improper dosing. The substitution of FENTORA for any other fentanyl product may result in fatal overdose.
>
> Due to the risk of respiratory depression, FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.[103]

344. When Cephalon launched Fentora on October 1, 2006, it picked up the playbook it developed for Actiq and simply substituted in Fentora: 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

[103] Fentora Drug Label, February 2013, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021947s008lbl.pdf

doctors that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

345. On May 1, 2007, just seven months after Fentora's launch, Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. He described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for even broader uses. He identified two "major opportunities"—treating breakthrough cancer pain and:

> 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. . . .
>
> We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication. . . . [opioids are] widely used in the treatment of . . . non-cancer patients. . . .
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[104]

346. Cephalon was well aware that physicians were prescribing Fentora for off-label

[104] See Cephalon Q1 2007 Earnings Call Transcript, Seeking Alpha (May 1, 2007, 8:48 PM EST) at 23, http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript?page=1.

uses. Cephalon's own market research studies confirm that its Fentora promotions were not focused on the physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

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

347. 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."[105]

348. 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

[105] Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007).

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.[106]

349. 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.

350. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a sponsored link on Google and other search engines for Fentora as misleading because it deceptively 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.[107]

351. 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.

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[106] *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) .

[107] Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (March 26, 2009).

352. 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*."[108]

353. Cephalon's conduct in marketing Actiq and Fentora for chronic non-cancer pain, despite their clear (and deadly) risks and unproved benefits, was an extension, and reaped the benefits, of Cephalon's generally deceptive promotion of opioids for chronic pain.

354. For example, Cephalon developed a guidebook called *Opioid Medications and REMS: A Patient's Guide*, which deceptively minimized the risks of addiction from the long-term use of opioids. Specifically, the guidebook claimed that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids," which is dangerously false. Cephalon distributed the guidebook broadly, and it was available to and intended to reach prescribers in Illinois.

(b) Cephalon's Deceptive Third-Party Statements.

355. 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.

[108] 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.

356. It did so by sponsoring pro-opioid front groups, misleading prescription 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.

(i) *FSMB – Responsible Opioid Prescribing.*

357. In 2007, for example, Cephalon sponsored and distributed through its sales representatives FSMB's *Responsible Opioid Prescribing*, which was drafted by "Medical Writer X," whose work for Janssen is described below. Medical Writer X was frequently hired by a consulting firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Medical Writer X's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

358. *Responsible Opioid Prescribing* was a signature piece of Medical Writer X's work and contained a number of deceptive statements. This publication claimed that because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.

359. *Responsible Opioid Prescribing* also misrepresented the likelihood of addiction by mischaracterizing drug-seeking behavior as "pseudoaddiction." It explained that "requesting drugs by name," engaging in "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding were all signs of "pseudoaddiction" and are likely the effects of undertreated pain, rather than true addiction. There is no scientific evidence to support the concept of pseudoaddiction, and any suggestion that addictive behavior masquerades as

"pseudoaddiction" is false.

360. Cephalon spent $150,000 to purchase copies of *Responsible Opioid Prescribing* in bulk. It then used its sales force to distribute these copies to 10,000 prescribers and 5,000 pharmacists nationwide.

(ii) *APF – Treatment Options: A Guide for People Living with Pain.*

361. Cephalon also exercised considerable control over the Front Group APF, which published and disseminated many of the most egregious falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, are described in detail below.

362. Documents indicate that Cephalon provided APF with substantial assistance in publishing deceptive information regarding the risks associated with the use of opioids for chronic pain. An April 3, 2008 Fentora Assessment Strategy Tactics Team Meeting presentation outlines Cephalon's strategy to prepare for a meeting at which the FDA Advisory Committee would consider expanding the indication of Fentora to include chronic, non-cancer pain. Cephalon prepared by "reaching out to third-party organizations, KOLs, and patients to provide context and, where appropriate, encourage related activity." First among the front groups listed was APF.

363. Cephalon was among the drug companies that worked with APF to persuade the Institute of Medicine of the National Academies (IOM) on issues related to chronic opioid therapy. APF President Will Rowe circulated a document to Cephalon and other drug company personnel that contained key message points and suggested that they "[c]onsider using this document in your communications with the members of the IOM Committee." According to Rowe, recipients should "consider this a working document which you can add to or subtract from." Rowe also advised that, if recipients "have an ally on that Committee," they should

"consider sharing this document with that person."

364. Cephalon personnel responded enthusiastically, with Cephalon's Associate Director for Alliance Development stating her belief that "the document does a good job of bringing together many important ideas." Cephalon reviewed and directed changes to this document, with the Cephalon Associate Director thanking Rowe "for incorporating the points we had raised." The close collaboration between Cephalon and APF on this project demonstrates their agreement to work collaboratively to promote the use of opioids as an appropriate treatment for chronic pain.

365. Cephalon's influence over APF's activities was so pervasive that APF's President, Will Rowe, even reached out to Defendants—including Cephalon—rather than his own staff to identify potential authors to draft an answer to an article critical of opioids that appeared in the Archives of Internal Medicine in 2011.

366. Cephalon also sponsored APF's *Treatment Options: A Guide for People Living with Pain*, starting in 2007. As described in Section III.E.1, it is rife with misrepresentations regarding the risks, benefits, and superiority of opioids.

(iii) *Misleading Continuing Medical Education.*

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

368. 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 non-cancer 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.[109]

369. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003, and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[110] 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.

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

371. 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

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[109] 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.

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

described 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."[111]

372. 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.

373. 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.[112] It recommends prescribing a "short-acting opioid" (e.g., morphine, hydromorphone, oxycodone) "when pain can be anticipated," or a rapid-onset opioid when it cannot. The only examples of rapid-onset opioids then on the market were oral transmucosal fentanyl citrate (*i.e.*, Actiq) or fentanyl effervescent buccal tablet (*i.e.*, Fentora): "Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients and are frequently prescribed to treat [breakthrough pain] in non-cancer patients as well."

374. *Optimizing Opioid Treatment for Breakthrough Pain* not only deceptively promoted Cephalon's drugs for off-label use, but also misleadingly portrayed the risks, benefits, and superiority of opioids for the treatment of chronic pain. For example, the CME

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

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

misrepresented that Actiq and Fentora would help patients regain functionality by advising that they improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. The CME also minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids. *Optimizing Opioid Treatment for Breakthrough Pain* was available online and was intended to reach Illinois prescribers.

375. Cephalon similarly used an educational grant to sponsor the CME *Breakthrough Pain: Improving Recognition and Management*, which was offered online between March 31, 2008, and March 31, 2009, by Medscape. The direct result of Cephalon's funding was a purportedly educational document that echoed Cephalon's marketing messages: the CME deceptively omitted Actiq's and Fentora's tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like Cephalon's *Optimizing Opioid Treatment* CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. This CME was available online and was intended to reach Illinois prescribers.

376. 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.[113] Cephalon paid to have this CME published in a "Special Report" supplement of the journal *Pain Medicine News* in 2009. The CME targeted a wide variety of

[113] Perry G. Fine, et al., *Long-Term Safety And Tolerability Of Fentanyl Buccal Tablet For The Treatment Of Breakthrough Pain In Opioid-Tolerant Patients With Chronic Pain: An 18-Month Study*, 40 J. Pain Symptom Mgmt. 747 (2010).

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.

377. 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 non-cancer 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 non-cancer 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.

(iv) *Misleading Science in Other Medical Literature.*

378. 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."

379. 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."[114] 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)-approved indication for Actiq. Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe non-cancer pain in both opioid-tolerant and opioid-nontolerant patients.

380. 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 non-cancer pain."* Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors state:

> […] 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.

381. 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

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

(including KOL Dr. Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of BTP to the chronic, non-cancer setting.[115] 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 non-cancer 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%).

382. 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 non-cancer 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.

383. 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 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."

384. 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

[115] 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).

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."[116]

385. 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 non-cancer 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."*[117]

386. 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.

387. 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.[118] (A 2012 article evaluating the then-current

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

[117] Perry G. Fine, et al., *supra* note 114.

[118] John Carreyrou, *supra* note 103.

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."[119])

388. 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 for activities including participating on speakers' bureaus, providing consulting services, and other services.

3. Janssen.

389. Janssen manufactures, and then markets, sells, and distributes the following Schedule II narcotics nationwide, including in Plaintiffs' member 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.

390. 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

[119] 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).

severe acute pain in patients 18 years of age or older."

391. 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."

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

(a) Janssen's Deceptive Direct Marketing.

(i) *Warnings by the FDA.*

393. Janssen employed an aggressive and misleading direct marketing campaign even despite regulatory scrutiny and repeated warnings. 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."

394. 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*.[120]

395. 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 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.

396. 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.

397. 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

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

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."

398. 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.[121]

[121] 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).

399. 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."
- "Significant improvement in social functioning."

400. 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."

401. 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.[122]

(ii) *Janssen's Deceptive Sales Training.*

402. Janssen promoted its branded opioids, including Duragesic, Nucynta, and Nucynta ER, through its sales representatives and a particularly active speakers program. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. Like the other Defendants, Janssen sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed identically across the country. These sales representatives were critical in transmitting Janssen's marketing strategies and talking points to individual prescribers. In 2011, at the peak of its effort to promote Nucynta ER, Janssen spent more than $90 million on detailing.

403. Even after receiving the letters described above, 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. Sales representatives in Illinois and nationwide were instructed 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 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. 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.

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

404. Janssen's sales force was compensated based on the number of Nucynta prescriptions written in each sales representative's territory. Janssen encouraged these sales representatives to maximize sales of Nucynta and meet their sales targets by relying on the false and misleading statements described above.

405. For example, Janssen's sales force was trained to trivialize addiction risk. A June 2009 Nucynta training module warns that physicians are reluctant to prescribe controlled substances like Nuycnta because of their fear of addicting patients, but this reluctance is unfounded because "the risks . . . are [actually] much smaller than commonly believed." Janssen also encouraged its sales force to misrepresent the prevalence of withdrawal symptoms associated with Nucynta. A Janssen sales training PowerPoint titled *Selling Nucynta ER and Nucynta* indicates that the "low incidence of opioid withdrawal symptoms" is a "core message" for its sales force. The message was touted at Janssen's Pain District Hub Meetings, in which Janssen periodically gathered its sales force personnel to discuss sales strategy.

406. This "core message" regarding a lack of withdrawal symptoms runs throughout Janssen's sales training materials. For example, Janssen's *Licensed to Sell* Facilitator's Guide instructs those conducting Janssen sales trainings to evaluate trainees, in part, on whether they remembered that "[w]ithdrawal symptoms after abrupt cessation of treatment with NUCYNTA ER were mild or moderate in nature, occurring in 11.8% and 2% of patients, respectively" and whether they were able to "accurately convey" this "core message." Janssen further claimed in 2008 that "low incidence of opioid withdrawal symptoms" was an advantage of the tapentadol molecule.

407. Similarly, a Nucynta Clinical Studies Facilitator's Guide instructs individuals training Janssen's sales representatives to ask trainees to describe a "key point"—that "83% of

patients reported no withdrawal symptoms after abruptly stopping treatment without initiating alternative therapy"—"as though he/she is discussing it with a physician."

408. This misrepresentation regarding withdrawal was one of the key messages Janssen imparted to employees in the *Retail ST 101 Training* delivered to Nucynta sales representatives. This training session was attended by more than 40 sales representatives from Janssen's Chicago sales district.

409. Indeed, training modules between 2009 and 2011 instruct training attendees that "most patients [who discontinued taking Nucynta] experienced no withdrawal symptoms" and "[n]o patients experienced moderately severe or severe withdrawal symptoms."

410. During the very time Janssen was instructing its sales force to trivialize the risks of addiction and withdrawal associated with the use of Nucynta to treat chronic pain, it knew or should have known that significant numbers of patients using opioids to treat chronic pain experienced issues with addiction. Janssen knew or should have known that its studies on withdrawal were flawed and created a misleading impression of the rate of withdrawal symptoms and, as a result, the risk of addiction.

411. The misleading messages and materials Janssen provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Plaintiffs' member communities.

(iii) *Janssen's Deceptive Speakers' Bureau Programs.*

412. Janssen also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives. Janssen's speakers worked from slide decks—which they were required to present—reflecting the deceptive information about

the risks, benefits, and superiority of opioids outlined above. For example, a March 2011 speaker's presentation titled *A New Perspective For Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* set out the following adverse events associated with use of Nucynta: nausea, vomiting, constipation, diarrhea, dizziness, headache, anxiety, restlessness, insomnia, myalgia, and bone pain. It completely omitted the risks of misuse, abuse, addiction, hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and other known, serious risks associated with chronic opioid therapy. The presentation also minimized the risks of withdrawal by stating that "more than 82% of subjects treated with tapentadol IR reported no opioid withdrawal symptoms."

413. An August 2011 speakers' presentation titled *New Perspectives in the Management of Moderate to Severe Chronic Pain* contained the same misleading discussion of the risks associated with chronic opioid therapy. It similarly minimized the risks of withdrawal by reporting that 86% of patients who stopped taking Nucynta ER "abruptly without initiating alternative opioid therapy" reported no withdrawal symptoms whatsoever. The same deceptive claims regarding risks of adverse events and withdrawal appeared in a July 2012 speaker's presentation titled *Powerful Pain Management: Proven Across Multiple Acute and Chronic Pain Models*.

(iv) *Janssen's Deceptive Unbranded Advertising.*

414. Janssen was aware that its branded advertisements and speakers' programs would face regulatory scrutiny that would not apply to its unbranded materials, so Janssen also engaged in direct, unbranded marketing. One such unbranded project was Janssen's creation and maintenance 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."[123] 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."[124]

415. 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 inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases."[125]

416. This website is available to and intended to reach Illinois prescribers and patients, including those in Plaintiffs' member communities.

(b) Janssen's Deceptive Third-Party Statements.

417. Janssen's efforts were not limited to directly making misrepresentations through its sales force, speakers bureau, and website. To avoid regulatory constraints and give its efforts an appearance of independence and objectivity, Janssen obscured its involvement in certain of its marketing activities by collaborating with key patient advocacy organizations to release

[123] Prescribe Responsibly, *Legal Notice* (last visited Oct. 11, 2018), http://www.prescribe responsibly.com/legal-notice.

[124] Prescribe Responsibly, *Use of Opioid Analgesics in Pain Management* (last visited Oct. 11, 2018), http://www.prescriberesponsibly.com/articles/opioid-pain-management.

[125] *Id*.; Prescribe Responsibly, *What a Prescriber Should Know Before Writing the First Prescription* (last visited Oct. 11, 2018), http://www.prescriberesponsibly.com/articles/before-prescribing-opioids.

misleading information about opioids.

(i) *AAPM and AGS – Finding Relief: Pain Management for Older Adults.*

418. 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.*

419. Janssen worked with front groups AAPM and AGS to create the patient education guide *Finding Relief*. In doing so, on information and belief, Janssen contracted with a medical publishing firm, Conrad & Associates, LLC. The content, on information and belief, was drafted by a writer ("Medical Writer X") hired by Conrad & Associates and funded by Janssen. On information and belief, these materials were reviewed, in detail, by Janssen's medical-legal review team, which conducted detailed reviews and gave him editorial feedback on his drafts, which was adopted in the published version.

420. On information and belief, Medical Writer X understood, without being explicitly told, that since his work was funded and reviewed by Janssen, the materials he was writing should aim to promote the sale of more drugs by overcoming the reluctance to prescribe or use opioids to treat chronic pain. On information and belief, he knew that the publication was undertaken in connection with the launch of a new drug and was part of its promotional effort. On information and belief, Medical Writer X knew of the drug company sponsoring the publication, and he would go to the company's website to learn about the drug being promoted. On information and belief, he also knew that his clients—including Janssen—would be most satisfied with his work if he emphasized that: (a) even when used long-term, opioids are safe and the risk of addiction is low; (b) opioids are effective for chronic pain; and (c) opioids are under-

prescribed because doctors are hesitant, confused, or face other barriers.

421. 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.[126]

422. 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 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.

423. *Finding Relief* is rife with the deceptive content described above. *Finding Relief* trivialized the risks of addiction describing a "myth" that opioids are addictive, and asserting as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

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

424. *Finding Relief* misrepresents that opioids increase function by featuring a man playing golf on the cover and listing examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). Before *Finding Relief* was published, the FDA had issued a warning letter for another drug's branded advertisement that suggested the drug caused "improvement in daily activities includ[ing]: walking on a flat surface, standing or sitting, climbing stairs, getting in and out of bed or bath, ability to perform domestic duties," finding these claims to be unsupported.[127] The functional claims contained in *Finding Relief* are textbook examples of Defendants' use of third parties to disseminate messages the FDA would not allow them to say themselves.

425. *Finding Relief* further misrepresented that opioids were safe at high doses by listing dose limitations as "disadvantages" of other pain medicines but omitting any discussion of risks from increased doses of opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."

426. Finally, *Finding Relief* deceptively overstated the risks associated with alternative forms of treatment. It juxtaposes the advantages and disadvantages of NSAIDs on one page, with the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "increase[d] . . . risk of heart attack and stroke." Conversely, the only adverse effects of opioids listed by *Finding Relief* are "upset

[127] Letter to King Pharmaceuticals Chairman Brian A. Markison, FDA, Division of Drug Marketing, Advertising, and Communications (March 24, 2008).

stomach or sleepiness," which the brochure claims will go away, and constipation. The guide never mentions addiction, overdose, abuse, or other serious side effects of opioids.

427. Janssen was not merely a passive sponsor of *Finding Relief*. Instead, Janssen exercised control over its content and provided substantial assistance to AGS and AAPM to distribute it. Thus, *Finding Relief* is considered labeling for Janssen's opioids within the meaning of 21 C.F.R. § 1.3(a).

428. AAPM, which is based in Chicago, purchased and distributed copies of *Finding Relief* to all of its members, including those who reside in its home city.

429. *Finding Relief's* author, Medical Writer X, later said it was clear, from his perch at the intersection of science and marketing, that the money paid by drug companies to the KOLs and professional and patient organizations with which he worked distorted the information provided to doctors and patients regarding opioids. The money behind these and many other "educational" efforts also, he believes, led to a widespread lack of skepticism on the part of leading physicians about the hazards of opioids. It also led these physicians to accept without adequate scrutiny published studies that, while being cited to support the safety of opioids, were, in fact, of such poor methodological quality that they would not normally be accepted as adequate scientific evidence.

(ii) *AGS – Misleading Medical Education.*

430. Janssen also worked with the AGS on another project—AGS's CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. As described above, these guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse" when the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely,

that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)." Based on Janssen's control over AGS's *Finding Relief*, Janssen also would have exercised control over this project as well.

(iii) *APF.*

431. Janssen also worked with APF to carry out its deceptive marketing campaign. Examples of APF's collaboration with Janssen are laid out below:

(a) *Let's Talk Pain.*

432. Most prominent among these efforts was the *Let's Talk Pain* website. Janssen sponsored *Let's Talk Pain* in 2009, acting in conjunction with APF, American Academy of Pain Management, and American Society of Pain Management Nursing, whose participation in the website Janssen financed and orchestrated.

433. Janssen exercised substantial control over the content of the *Let's Talk Pain* website. Janssen regarded *Let's Talk Pain* and *Prescribe Responsibility*, the website discussed above, as integral parts of Nucynta's launch.

434. Janssen also exercised its control over *Let's Talk Pain*. Janssen was able to update the *Let's Talk Pain* website to describe its corporate restructuring and Janssen personnel asserted their control over "video additions" by reviewing and editing the interview touting the functional benefits of opioids. Given its editorial control over the content of *Let's Talk Pain*, Janssen was at all times fully aware of—and fully involved in shaping—the website's content.[128]

435. *Let's Talk Pain* contained a number of the misrepresentations outlined above.

436. For example, *Let's Talk Pain* misrepresented that the use of opioids for the

[128] It bears noting that Janssen does not publicly identify its role in creating *Let's Talk Pain*'s content. Instead, *Let's Talk Pain* represents that "coalition members" develop the content that appears on the website and lists Janssen as the only sponsor of that coalition.

treatment of chronic pain would lead patients to regain functionality. *Let's Talk Pain* featured an interview claiming that opioids were what allowed a patient to "continue to function." This video is still available today on YouTube.com and is accessible to Illinois prescribers and patients.

437. *Let's Talk Pain* in 2009 also promoted the concept of pseudoaddiction, which it described as patient behaviors that may occur when pain is under-treated" but differs "from true addiction because such behaviors can be resolved with effective pain management" (emphasis added).

438. The *Let's Talk Pain* website is available to and intended to reach Illinois prescribers and patients, including those in Plaintiffs' member communities.

(b) *Exit Wounds.*

439. Janssen also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by "Medical Writer X." It is fully representative of his work on behalf of drug companies.

440. Janssen gave APF substantial assistance in distributing *Exit Wounds* in Illinois and throughout the nation by providing grant money and other resources.

4. Endo.

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

442. 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."

443. However, oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.[129]

444. 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."

445. 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.

446. According to Endo's annual reports, sales of Opana and Opana ER regularly

[129] John Fauber & Kristina Fiore, *Opana Gets FDA Approval Despite History of Abuse, Limited Effectiveness in Trials*, Milwaukee J. 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/.

generate several hundred million dollars in annual revenue for the company.

(a) Endo's Deceptive Direct Marketing.

447. Endo's promotion of Opana ER relied heavily on in-person marketing, including to Illinois prescribers. Endo had an aggressive detailing program, with its sales representatives making nearly 72,000 visits to prescribers nationwide to detail Opana ER in the first quarter of 2010 alone. Between 2007 and 2013, Endo spent between $3 million and $10 million each quarter to promote opioids through its sales force.

448. Endo's sales representatives, like those of the other Defendants, targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in transmitting Endo's marketing strategies and talking points to individual prescribers.

449. Endo specifically directed its sales force to target physicians who would prescribe its drugs to treat chronic pain.

450. Endo knew that its marketing reached physicians —repeatedly—because it tracked their exposure.

451. Endo also knew that its marketing messages were successfully imparted to the physicians it targeted. Although Opana ER always has been classified under Schedule II as a drug with a "high potential for abuse," the largest single perceived advantage of Opana ER, according to a survey of 187 physicians who reported familiarity with the drug, was "perceived low abuse potential."

452. Nationally, the physicians Endo targeted for in-person marketing represented approximately 84% of all prescriptions for Opana ER in the first quarter of 2010. Endo also observed that the prescribers its sales representatives visited wrote nearly three times as many

prescriptions per month for Opana ER as those physicians who were not targeted for Endo's marketing—7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly 30 prescriptions per month.

453. Endo also leaned heavily on its speakers' bureau programs. In 2008 alone, Endo spent nearly $4 million to promote up to 1,000 speakers' programs around the country. In 2012, at least 13 speakers' programs devoted to Opana ER took place in Illinois, up from 8 in 2011. These programs were attended by sales representatives as marketing, rather than educational, events.

454. Endo trained its sales force and recruited speakers for its speakers' bureau presentations to make a number of misrepresentations to physicians nationwide, including to physicians in Illinois. Endo's sales representatives were trained to represent to these prescribers that Opana ER would help patients regain function they had lost to chronic pain; that Endo opioids had a lower potential for abuse because they were "designed to be crush resistant," even though the "clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER;" and that drug seeking behavior was a sign of undertreated pain rather than addiction.

(i) *Endo falsely marketed Opana ER as crush-resistant.*

455. 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."

456. 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.

457. Endo's claims about the crush-resistant design of Opana ER also made their way to the company's press releases. A January 2013 article in *Pain Medicine News*, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible nationwide.

458. Endo's speakers' bureau presentations included the very same misrepresentations Endo disseminated through its sales representatives. This was a key point in distinguishing Opana ER from competitor drugs. Although Endo mentioned that generic versions of oxymorphone were available, it instructed speakers to stress that "[t]he generics are not designed to be crush resistant."

459. 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."[130]

460. 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

[130] 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

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."

461. 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.

462. 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."[131] The CDC specifically attributed the outbreak to the injection of 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."

463. 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."

464. The State of New York revealed evidence showing that Endo had known about

[131] CDC, Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs, (last visited Oct. 11, 2018), https://emergency.cdc.gov/han/han00377.asp.

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 representatives 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.

465. 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.[132]

466. 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.

467. 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

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

resistant."[133] 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.

468. 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."[134]

(ii) *Endo deceptively minimized the risks of addiction associated with chronic opioid therapy.*

469. Endo's sales training and the promotional materials distributed by its sales representatives also minimized the risk of addiction. For example, Endo circulated an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which implied to persons providing care to chronic pain patients that addiction was not a substantial concern by stating that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem." This program was downloadable from Endo's website and accessible to prescribers nationwide.

470. The Office of the Attorney General of New York 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

[133] *Id.* at 6.

[134] *Id.*

reformulated Opana ER could be ground and chewed.

471. 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.

472. 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.

473. 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.

(iii) *Endo deceptively implied that chronic opioid therapy would improve patients' ability to function.*

474. In addition to their deceptive messages regarding addiction, Endo's promotional materials and sales trainings also misleadingly claimed that patients using opioids for the long-term treatment of chronic pain would experience improvements in their daily function.

475. A sales training video dated March 8, 2012 that Endo produced and used to train its sales force makes the same types of claims. A patient named Jeffery explains in the video that

he suffers from chronic pain and that "chronic pain [. . .] reduces your functional level." Jeffery claims that after taking Opana ER, he "can go out and do things" like attend his son's basketball game and "[t]here's no substitute for that." This video was shown to Endo's sales force, which adopted its misleading messaging in its nationwide sales approach, including the approach it used in Illinois.

476. Claims of improved functionality were central to Endo's marketing efforts for years.

477. Endo further misled patients and prescribers by downplaying the risks of opioids in comparison to other pain relievers. For example, it distributed in Illinois and elsewhere a presentation titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. This study held out as a representative example one patient who had taken NSAIDs for more than eight years and, as a result, developed "a massive upper gastrointestinal bleed." The presentation recommended treating this patient with opioids instead. By focusing on the adverse side effects of NSAIDs, while omitting discussion of serious side effects associated with opioids, this presentation misleadingly portrayed the comparative risks and benefits of these drugs.

478. 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.

(b) Endo's Deceptive Third-Party Statements

479. Like the other Defendants, Endo provided substantial funding to purportedly neutral medical organizations to produce false and misleading materials concerning the risks and benefits of prescription opioids. Prior to, but in contemplation of, the 2006 launch of Opana ER, in 2008, Endo spent $1 million per year to attend conventions of these pro-opioid medical societies, including meetings of AAPM, APS, and the American Society of Pain Management Nursing ("ASPMN").

(i) *APF*

480. One of the societies with which Endo worked most closely was APF. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC"). Endo was one of the APF's biggest financial supporters, and Endo provided more than half of the $10 million APF received from opioid manufacturers during its lifespan. Endo spent $1.1 million on the NIPC program in 2008 alone, funding earmarked, in part, for the creation of CME materials that were intended to be used over and over again.

481. Nowhere was Endo's relationship with APF closer than with its sponsorship of the NIPC. Before being taken over by APF, the NIPC was sponsored by Professional Postgraduate Services, but that company was determined to be a "commercial interest" by the ACCME and could no longer serve as a sponsor. In response, Endo reached out to APF.

482. Behind the scenes, Endo exercised substantial control over NIPC's work. Endo exerted its control over NIPC by funding NIPC and APF projects; developing, specifying, and reviewing content; and taking a substantial role in distribution of NIPC and APF materials, which in effect determined which messages were actually delivered to prescribers and consumers. As described below, Endo projected that it would be able to reach tens of thousands

of prescribers nationwide through the distribution of NIPC materials.

483. From 2007 until at least 2011, Endo also meticulously tracked the distribution of NIPC materials, demonstrating Endo's commercial interest in and access to NIPC's reach. Endo knew exactly how many participants viewed NIPC webinars and workshops and visited its website, *Painknowledge.com*. Endo not only knew how many people viewed NIPC's content, but what their backgrounds were (e.g., primary care physicians or neurologists). Endo's access to and detailed understanding of the composition of the audience at these events demonstrates how deeply Endo was involved in NIPC's activities. Moreover, Endo tracked the activities of NIPC—ostensibly a third party—just as it tracked its own commercial activity.

484. Endo worked diligently to ensure that the NIPC materials it helped to develop would have the broadest possible distribution.

485. In short, NIPC was a key piece of Endo's marketing strategy.

486. Endo's influence over APF's activities was so pervasive that APF President Will Rowe even reached out to Defendants—including Endo—rather than his own staff to identify potential authors to answer an article critical of opioids that appeared in the *Archives of Internal Medicine* in 2011. Personnel from Defendants Purdue, Endo, Janssen, and Cephalon worked with Rowe to formulate APF's response. The response suggested by Defendants was the one that APF ultimately published.

(a) *Misleading Medical Education*

487. NIPC distributed a series of eNewsletter CMEs focused on "key topic[s] surrounding the use of opioid therapy" and sponsored by Endo. These newsletters were edited by KOL Dr. Perry Fine and also listed several industry-backed KOLs, including Dr. Webster, as individual authors.

488. Endo documents made clear that the persuasive power of NIPC speakers was directly proportional to their perceived objectivity.

489. The materials made available on and through NIPC included misrepresentations. For example, Endo worked with NIPC to sponsor a series of CMEs titled *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult*. These CMEs misrepresented the prevalence of addiction by stating that opioids have "possibly less potential for abuse" in elderly patients than in younger patients, even though there is no evidence to support such an assertion. Moreover, whereas withdrawal symptoms are always a factor in discontinuing long-term opioid therapy, *Persistent Pain in the Older Adult* also misleadingly indicated that such symptoms can be avoided entirely by tapering the patient's does by 10-20% per day for ten days. *Persistent Pain in the Older Patient*, for its part, made misleading claims that opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

490. NIPC webcast these CMEs from its own website, where they were available to and were intended to reach prescribers nationwide, including those in Plaintiffs' network. For example, Endo hired a Philadelphia, Pennsylvania-based KOL to deliver the CME *Persistent Pain in the Older Adult* at the Marriott Chicago Downtown on Wednesday, May 18, 2011, with 41 prescribers in Chicago in attendance. Endo hired a New York-based KOL to deliver the CME *Persistent Pain in the Older Patient* on April 27, 2010 at the Westin Michigan Avenue in Chicago, with 54 attendees. An email invitation to the event and other NIPC programs was sent to "all healthcare professionals" in APF's database.

(b) *Painknowledge.com*

491. Working with NIPC enabled Endo to make a number of misleading statements through the NIPC's website, *Painknowledge.com*, which touted itself as "a one-stop repository

for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches."[135] Endo tracked visitors to *PainKnowledge.com* and used *Painknowledge.com* to broadcast notifications about additional NIPC programming that Endo helped to create.

492. True to APF's word, *Painknowledge.com* misrepresented that opioid therapy for chronic pain would lead to improvements in patients' ability to function. Specifically, in 2009 the website instructed patients and prescribers that, with opioids, a patient's "level of function should improve" and that patients "may find [they] are now able to participate in activities of daily living, such as work and hobbies, that [they] were not able to enjoy when [their] pain was worse."

493. *Painknowledge.com* also deceptively minimized the risk of addiction by claiming that "[p]eople who take opioids as prescribed usually do not become addicted." *Painknowledge.com* did not stop there. It deceptively portrayed opioids as safe at high doses and also misleadingly omitted serious risks, including the risks of addiction and death, from its description of the risks associated with the use of opioids to treat chronic pain. 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.

494. Endo was the sole funder of *Painknowledge.com*, and it continued to provide that funding despite being aware of the website's misleading contents.

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[135] PainKnowledge, *AboutPainKnowledge.org* (last visited Oct. 12, 2018), http://web.archive.org/web/20130513010647/http://www.painknowledge.org/aboutpaink.aspx.

(c) *Exit Wounds*

495. Finally, Endo also sponsored APF's publication and distribution of *Exit Wounds*, a publication aimed at veterans that, as described in Section III.E.1, also contained a number of misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain.

496. *Exit Wounds* was drafted by "Medical Writer X," whose extensive work for Janssen is described above. As discussed, Medical Writer X was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors. This, in combination with Endo's exercised dominance over APF and the projects it undertook in an effort to promote the use of opioids to treat chronic pain, gave Endo considerable influence over the work of Medical Writer X and over APF. Further, by paying to distribute *Exit Wounds*, Endo endorsed and approved its contents.

497. Along with Janssen and Purdue, Endo also provided grants to the APF to distribute *Exit Wounds*, discussed above.

(ii) *Other Front Groups: FSMB, AAPM, and AGS*

498. In addition to its involvement with APF, Endo worked closely with other third-party front groups and KOLs to disseminate deceptive messages regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. As with certain APF publications, Endo in some instances used its sales force to directly distribute certain publications by these front groups and KOLs, making those publications "labeling" within the meaning of 21 C.F.R. § 1.3(a).

499. In 2007, Endo sponsored FSMB's *Responsible Opioid Prescribing*, which, as

described in Section III.D, in various ways deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* was drafted by "Medical Writer X."

500. Endo spent $246,620 to help FSMB distribute *Responsible Opioid Prescribing.* Endo approved this book for distribution by its sales force. Based on the uniform and nationwide character of Endo's marketing campaign, and the fact that Endo purchased these copies specifically to distribute them, these copies were distributed to physicians nationwide, including physicians in Plaintiffs' network.

501. In December 2009, Endo also contracted with AGS to create a CME to promote the 2009 guidelines titled the *Pharmacological Management of Persistent Pain in Older Persons* with a $44,850 donation. As described above, these guidelines misleadingly claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse," since the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)" when in reality, opioid therapy was an appropriate treatment only for a subset of those patients, as Endo's FDA-mandated labels recognized.

502. AGS's grant request to Endo made explicit reference to the CME Endo was funding. Endo thus knew full well what content it was paying to distribute, and was in a position to evaluate that content to ensure it was accurate, substantiated, and balanced before deciding whether to invest in it.

503. Endo also worked with AAPM, with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its

publications.

504. A talk written by Endo in 2009, approved by Endo's Medical Affairs Review Committee,[136] and given by a Chicago-area KOL, titled *The Role of Opana ER* in the Management of Chronic Pain, includes a slide titled Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain. That slide cites the AAPM/APS Guidelines, which contain a number of misstatements as outlined in Section C above, while omitting their disclaimer regarding the lack of supporting evidence. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

(iii) *Key Opinion Leaders and Other Misleading Science*

505. Endo also sought to promote opioids for the treatment of chronic pain through the use of key opinion leaders and biased, misleading science.

506. In the years that followed, Endo sponsored articles, authored by an Endo consultant and Endo employees, which argued that the metabolic pathways utilized by Opana ER made it less likely than other opioids to result in drug interactions in elderly low back and osteoarthritis pain patients. In 2010, Endo directed its publication manager to reach out to a list of consultants conducting an ongoing Endo-funded study, to assess their willingness to respond

[136] Although they were given slightly different names by each Defendant, each Defendant employed a committee that would review and approve materials for distribution. These committees included representatives from all relevant departments within Defendants' organizations, including the legal, compliance, medical affairs, and marketing departments. The task of these review committees was to scrutinize the marketing materials Defendants planned to distribute and to ensure that those materials were scientifically accurate and legally sound. Tellingly, these committees were called to review only materials that created a potential compliance issue for the company, an implicit recognition by Defendants that they ultimately would be responsible for the content under review.

to an article[137] that Endo believed emphasized the risk of death from opioids, "without [] fair balance."[138]

507. Endo's reliance on flawed, biased research is also evident in its 2012 marketing materials and strategic plans.

508. Endo also worked with various KOLs to disseminate various misleading statements about chronic opioid therapy. For example, in 2014, Endo issued a patient brochure titled *Understanding Your Pain: Taking Oral Opioid Analgesics*.[139] It was written by nurses Margo McCaffery and Chris Pasero, 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.

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[137] Susan Okie, *A Flood of Opioids, a Rising Tide of Deaths*, 363 New Engl. J. Med. 1981 (2010), finding that opioid overdose deaths and opioid prescriptions both increased by roughly 10-fold from 1990 to 2007.

[138] Endo did manage to get a letter written by three of those researchers, which was not published.

[139] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

509. The pamphlet also deceptively minimized the risks of addiction by stating that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems," implying that patients who are taking opioids for pain are not at risk of addiction.

510. *Understanding your Pain: Taking Oral Opioid Analgesics* also misleadingly omitted any description of the increased risks posed by higher doses of opioid medication. Instead, in a Q&A format, the pamphlet asked "[i]f I take the opioid now, will it work later when I really need it?" and responded that "[t]he dose can be increased . . . [y]ou won't 'run out' of pain relief."

511. Dr. Portenoy received research support, consulting fees, and honoraria from Endo for editing *Understanding Your Pain* and other projects.

512. Endo similarly distributed a book written by Dr. Lynn Webster titled *Avoiding Opioid Abuse While Managing Pain*, which stated that in the face of signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."

513. Based on the nationwide and uniform character of Endo's marketing, and the book's approval for distribution, this book was available to and was intended to reach prescribers in Plaintiffs' network.

514. In April 2007, Endo also 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*.[140] 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

[140] 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.

> prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.

515. 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."*

516. 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."

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

5. Mallinckrodt.

518. Mallinckrodt manufactures, and then markets, sells and distributes pharmaceutical drugs nationwide, including in Plaintiffs' member 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 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.

519. 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.

520. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.[141]

(a) Mallinckrodt's Deceptive Direct Marketing

521. Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement. Mallinckrodt did so through a broad array of marketing channels, including its website, sales force, and unbranded communications, such as those distributed through the "C.A.R.E.S. Alliance" it created and led.

522. In 2010, Mallinckrodt created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt describes

[141] 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.

C.A.R.E.S as its own advocacy program, and promised "[t]hrough the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take."

523. The C.A.R.E.S. Alliance publicly describes itself as "[c]reated with leading pain experts through a scientific process" and offering "free resources" to "promote safe prescribing, dispensing, use, storage, and disposal" of opioid pain medications. It further described the "safe-use programs and voluntary tools" it developed as "grounded in science and research." The

524. "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

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

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medications, including medications not used for pain, and is easily remedied."

- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "[I]n our experience, the issue of tolerance is overblown."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

526. Mallinckrodt's former parent Company, Covidien, published a patient resource, "Opioid Safe Use and Handling Guide," which stated that: "Addiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a healthcare provider, but it can occur;" and "Taking more than your prescribed amount of medication to treat your pain is not the same as addiction, but it can be very dangerous."

(b) Mallinckrodt's Deceptive Third-Party Statements

527. Like many of the other 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."[142]

528. 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 alcohol or drug problems is rare."[143]

529. 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."

530. 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."[144]

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

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[142] Pain-Topics.org (last visited Oct. 12, 2018), https://web.archive.org/web/20120502042343/http://pain-topics.org.

[143] 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.

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

6. Actavis.

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

533. 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.

(a) Actavis Deceptive Direct Marketing

534. Actavis's sales representatives targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives, or detailers, were critical in delivering Actavis's marketing strategies and talking points to individual prescribers. At the peak of Actavis's promotional efforts in 2011, the company spent $6.7 million on "detailing."

535. 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.

(i) *Actavis's Deceptive Sales Training*

536. Actavis's strategy and pattern of deceptive marketing is evident by looking at its training materials.

537. This sales training module 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.

538. The sales training also noted that there were various "signs associated with substance abuse," including past history or family history of substance or alcohol abuse, frequent requests to change medication because of side effects or lack of efficacy, and a "social history of dysfunctional or high-risk behaviors including multiple arrests, multiple marriages, abusive relationships, etc." This is misleading, as noted above, because it implies that only patients with these kinds of behaviors and history become addicted to opioids.

539. Further, the sales training neglected to disclose that no risk-screening tools related to opioids have ever been scientifically validated. Rather, the AHRQ recently issued an Evidence Report that could identify "[n]o study" that had evaluated the effectiveness of various risk mitigation strategies—including the types of patient screening implied in Actavis's sales training—on outcomes related to overdose, addiction, abuse or misuse.

540. 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.

541. Finally, the 2010 national training materials trivialized the harms associated with opioid withdrawal by explaining that "[p]hysical dependence simply requires a tapered

withdrawal should the opioid medication no longer be needed." This, however, overlooks the fact that the side effects associated with opiate withdrawal are severe and a serious concern for any person who wishes to discontinue long-term opioid therapy.

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

543. 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."

544. Actavis also commissioned surveys of prescribers to ensure Kadian sales representatives were promoting the "steady-state" message. That same survey—paid for and reviewed by Actavis—found repeated instances of prescribers being told by sales representatives that Kadian had low potential of abuse or addiction. This survey also found that prescribers were influenced by Actavis's messaging. A number of Kadian prescribers stated that they prescribed Kadian because it was "without the addictive potential" and wouldn't "be posing high risk for addiction." As a result, Actavis's marketing documents celebrated a "perception" among doctors that Kadian had "low abuse potential."

545. As mentioned above, these guidelines deceptively concluded that the risk of

addiction is manageable for patients regardless of past abuse histories.

(ii) *Actavis Deceptive Speakers' Training*

546. 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."

547. 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.

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

549. 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.

550. 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.

551. 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.

552. 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."

(b) Actavis's Deceptive Third-Party Statements

553. The misleading messages and training materials Actavis provided to its sales force and speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and alternatives.

554. 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."

555. 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."

556. 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.

557. 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."

558. 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."

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

560. Articles matching Actavis's descriptions later appeared in the Journal of Pain and the Journal of the American Geriatrics Society (AGS).

F. Manufacturer Defendants' Deceptive Marketing Caused An Increase In Opioid Prescribing Nationwide, Including In Plaintiffs' Networks

561. From 1980 to 2000, opioid prescriptions for chronic pain visits doubled. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide. During 2009, they provided 83 million more. After a steady increase in the overall national opioid prescribing rate starting in 2006, the total number of prescriptions dispensed nationwide peaked in 2012 at more than 255 million and a prescribing rate of 81.3 prescriptions per 100 persons.[145] Today, almost three times as many opioids are prescribed in the United States as compared to 1999.[146]

562. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010—even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications ***decreased***.

563. The opioid prescription rate in the state of Illinois likewise peaked in 2012, as it did in Cook County and nearly every Illinois county in which Plaintiffs' members reside.

564. In 2016, for every 10 Illinois residents, 1.56 individuals filled at least one opioid prescription. According to the Illinois Prescription Drug Monitoring Database, the number of individuals filling at least one opioid prescription in Illinois remained comparatively consistent each year from 2008 to 2015, but did show a decrease between 2015 and 2016, dipping below 200,000 patients for the first time during the period studied. This was consistent with national trends indicating reductions in opioid prescribing in recent years as compared to peak prescribing

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[145] Paulozzi, L. J., Mack, K. A., Hockenberry, J. M., *Vital signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepine—United States, 2012*, Morbidity and Mortality Weekly Report, 63, 563–8 (July 4, 2014).

[146] Guy, F. P., Zhang, K., Bohm, M. K., Losby, J., Lewis, B., Young, R., Murphy, L., & Dowell, D, *Vital signs: Changes in opioid prescribing in the United States, 2006-2015.* Morbidity and Mortality Weekly Report, 66(26), 697-704 (July 7, 2017).

activity in the late 2000's and early 2010's.

565. The nationwide opioid epidemic is a volume-driven epidemic. The demand for prescription opioids throughout the last two decades corresponds with, and was caused by, Manufacturer Defendants' massive marketing push. Defendants' spending nationwide on marketing of opioids—including all of the drugs at issue here—stood at more than $20 million per quarter and $91 million annually in 2000. By 2011, that figure hit its peak of more than $70 million per quarter and $288 million annually, a more than three-fold increase. In 2011, Manufacturer Defendants collectively spent over $14 million on medical journal advertising of opioids alone—nearly triple what they spent in 2001.

566. By far the largest component of this spending was opioid drug makers' detailing visits to individual doctors, with total detailing expenditures more than doubling between 2000 and 2014 and now standing at $168 million annually. However, the influence of Manufacturer Defendants' deceptive marketing extends far beyond the physicians who were detailed by Manufacturer Defendants' sales representatives. Practitioners began writing opioid prescriptions to treat chronic pain because Manufacturer Defendants made the practice the new normal—patients demanded opioids and the medical profession more generally had adopted Defendants' message that the appropriate treatment of pain required such drugs.

567. Through their direct promotional efforts, along with those of the third-party front groups and KOLs they assisted and controlled, and whose seemingly objective materials they distributed, Manufacturer Defendants accomplished exactly what they set out to do: change the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain. As a result, health care practitioners began prescribing opioids long-term to treat chronic pain. But for the misleading information disseminated by

Manufacturer Defendants, health care practitioners in Plaintiffs' networks would not have prescribed opioids as medically necessary or reasonably required address chronic pain.

568. Manufacturer Defendants' marketing and misinformation caused health care practitioners to prescribe and Plaintiffs (through their benefits programs) to pay for prescriptions of opioids to treat chronic pain. Manufacturer Defendants' unbranded marketing also caused health care practitioners to write (and Plaintiffs to pay for) prescriptions of opioids for chronic pain that were filled with drugs sold by other manufacturers, not named in this Complaint.

569. Manufacturer Defendants set out to change the medical and general consensus supporting chronic opioid therapy so that practitioners would prescribe and insurance providers would pay for long-term prescriptions of opioids to treat chronic pain. The fact that Plaintiffs would shoulder the cost of these prescriptions is both the foreseeable and intended consequence of Manufacturer Defendants' fraudulent marketing scheme.

570. Each Manufacturer Defendant's[147] promotional spending reflects its participation in this marketing push. Between 2000 and 2011:

- Actavis's promotional spending, which was virtually non-existent in the 2004-2008 period, sharply rose beginning in 2009 to a quarterly peak of nearly $3 million at one point in 2011 (and nearly $7 million for the year);
- Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year);
- Endo's quarterly spending steadily climbed from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year);
- Janssen's quarterly spending dramatically rose from less than $5 million in 2000

[147] Plaintiffs do not have information concerning Mallinckrodt's promotional spending.

to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011);

- Purdue's quarterly spending notably decreased from 2000 to 2007 as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year).

571. Commensurate with Manufacturer Defendants' heavy spending on promoting opioids and the concomitant uptick in nationwide prescribing patterns, Plaintiffs' own spending on opioid prescription coverage—through IRMA's workers' compensation program and IPBC's health insurance plans—has increased dramatically.

IV. Distributor Defendants Willfully Failed to Perform Basic Diligence In The Wholesale Distribution Of Prescription Opioids In Order To Acquire Higher Profits For Themselves And Manufacturer Defendants.

572. 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.

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

574. On the supply side, due diligence on orders of prescription opioids is crucial to prevent "diversion" of pills into non-legitimate channels. "Diversion" occurs whenever the pills are able to be redirected along the supply chain 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.

575. Drug distributors play a distinct and important role in checking the misuse and diversion of prescription opioids. Because they are uniquely situated in the supply chain as an intermediary between the drug manufacturers (where the supply chain starts) and the points of sale/distribution, drug distributors are a "chokepoint" in the drug supply chain that can monitor

and analyze orders of controlled substances and report orders as "suspicious" to law enforcement agencies.

576. For this reason, federal law requires distributors like the Distributor Defendants to investigate, report, and stop suspicious orders of prescription opioids. Congress created a mechanism to guard against the diversion of highly addictive, dangerous substances with the Controlled Substance Act of 1970. In creating the Controlled Substance Act, Congress recognized that distributors are "one of the key components of the distribution chain" and "must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[148]

577. Recognizing the importance of regulating the distribution of opiates within the state, Illinois adopted its own Controlled Substances Act. 720 ILCS 570 *et seq.* The Legislature recognized "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100. It adopted a distribution control system aimed at, among other goals, limiting access to drugs and deterring their use. *Id.*; *see also* 720 ILCS 570/201(h) (requiring registrants to "provide effective controls and procedures to guard against theft and diversion" of controlled substances). Unsurprisingly, the Illinois Controlled Substances Act—which was designed to "unify where feasible . . . the efforts of [Illinois] to conform with" the federal system, 720 ILCS 570/100—aligns in large part with the federal Controlled Substances Act.

[148] Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health, Sept. 27, 2006, p. 1 ("September 27, 2006 Letter") (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-51 (D.D.C.).)

578. The Controlled Substance Act combats diversion by requiring that "all legitimate handlers of controlled substances must obtain a DEA [Drug Enforcement Administration] registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion."[149] "Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances…from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the [Controlled Substances Act] collapses."[150]

579. Likewise, Illinois passed the Wholesale Drug Distribution Licensing Act, which sets minimum licensure requirements for distributors, including recordkeeping requirements. 225 ILCS 120/1 *et seq.*; *see also* Ill. Admin. Code § 1510.50. It empowers the Illinois Department of Financial and Professional Regulation to impose fines and revoke licenses of those that "[f]ail[] to adequately secure controlled substances or other prescription drugs from diversion." 225 ILCS 120/55(a)(16); *see also* 720 ILCS 570/303 (the Illinois Controlled Substances Act similarly allows the Department to fine or revoke the license of a licensee that "failed to provide effective controls against the diversion of controlled substances in other than legitimate medical, scientific or industrial channels").

580. Prior to the establishment of the DEA, the Bureau of Narcotics and Dangerous Drugs issued regulations in 1971 in accordance with the objectives of the Controlled Substances

[149] September 27, 2006 Letter, p. 1.

[150] Declaration of Joseph Rannazzisi, ¶ 10 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-2 (D.D.C. February 10, 2012).)

Act.[151] The regulations, among other things, require distributors to maintain complete and accurate records of all controlled substances transactions, that is, at any point controlled substances are manufactured, imported, sold, received, delivered, exported, or otherwise disposed of (such as to hospitals, retail pharmacies, practitioners, etc.).[152] *See also* Ill. Admin. Code § 1510.50(f)(1) (requiring distributors to "establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition prescription drugs").

581. The regulations also require distributors to report their controlled substances transactions to the DEA, which monitors the distribution of controlled substances using an automated, comprehensive reporting system known as the Automation of Reports and Consolidation Orders System ("ARCOS").[153] Using the data reported by commercial distributors like Distributor Defendants, ARCOS summarizes the transactions into reports that federal and state government agencies (including the DEA) can use to identify potential cases of diversion. This reporting system is crucial for law enforcement to be able to investigate suspicious orders of controlled substances that, as discussed above, carry a high risk of abuse.

582. Distributors are also required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."[154] "Suspicious" orders include "orders of unusual size, orders deviating substantially

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[151] The DEA was established within the Department of Justice by Executive Order on July 1, 1973. See Reorganization Plan No. 2 of 1973, 3 C.F.R. 785 (1971 – 1975 Comp.) reprinted at 21 U.S.C. § 801.

[152] *See* 21 U.S.C. § 827(a)(3); 21 C.F.R.1304.21(a); *id.* 1304.22(b).

[153] 21 U.S.C. § 827(d)(1); 21 C.F.R. §§ 1304.33(d)–(e); *see also* September 27, 2006 Letter, p. 2.

[154] 21 C.F.R. § 1301.74(b).

from a normal pattern, and orders of unusual frequency."[155]

583. Commensurate with the obligation to identify and report suspicious orders is the distributor's obligation to conduct a meaningful investigation into the customer and the order in question to resolve the suspicion (*i.e.*, to verify that the order is actually being used to fulfill legitimate medical needs) before distributing the order.[156] "Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order."[157]

584. In addition to its own laws and regulations as described above, the State of Illinois expressly 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).

585. Distributor Defendants have been given ample guidance on the duties attendant to its role as a distributor of massive amounts of opioids, namely its obligation to identify and report suspicious orders within its distribution channels. The purpose and proper implementation of suspicious order reporting programs was discussed by the industry's own trade association, the Healthcare Distribution Management Association ("HDMA," now commonly referred to as

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[155] *Id.*

[156] 21 U.S.C. § 823(b) & (e).

[157] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 211 (D.C. Cir. 2017) (quoting 21 U.S.C. § 823(b), (e)).

"HDA")—of which the Distributor Defendants are members—in its "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," published in 2008.

586. The HDMA also recognizes the vital role that distributors play in curbing opioid abuse: "[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 HDMA has further acknowledged that drug distributors "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."[158]

587. Through the above statements made on their behalf by the HDMA, Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations. Still, as explained below, at various times over the past several years, each Distributor Defendant has ignored its obligations by supplying opioids to suspicious physicians and pharmacies and failing to report suspicious orders to the DEA.

588. The DEA launched an industry-specific anti-diversion initiative in 2005 called the "Distributor Initiative Program" with the goal to "educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders."[159] Through this

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

[159] *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before H. Comm. on Energy & Commerce, Subcomm. on Health*, 113th Cong., 2014, Statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.

program, the DEA "educates distributors about their obligations under the [Controlled Substances Act], as well as provides registrants with current trends and 'red flags' that might indicate that an order is suspicious."[160] The DEA has briefed each Distributor Defendant about concerns regarding illegal pharmacy operations and rogue pain clinics.

589. The DEA has also spelled out in detail to Distributor Defendants the purpose and proper implementation of suspicious order reporting programs in three letters that the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer or distributor of controlled substances, including each Distributor Defendant, on September 27, 2006, February 7, 2007, and December 27, 2007. [161]

590. The September 27, 2006 Letter reminded registrants that they "share responsibility for maintaining appropriate safeguards against diversion" and "given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[162]

591. The September 27, 2006 Letter also provided that "in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid

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[160] *Id.*

[161] *See* September 27, 2006 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."); *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) ("December 27, 2007 Letter"), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, dkt. 14-8 (D.D.C. Feb. 10, 2012); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Feb. 7, 2007.

[162] September 27, 2006 Letter, p. 2.

filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[163] In the letter, the DEA also provided examples of indicia of diversion, including orders of excessive quantities of a limited variety of controlled substances, disproportionate ratios of controlled substances to non-controlled prescription drugs, excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs, and orders of the same controlled substance from multiple distributors. The letter went on to offer several suggested questions that distributors could ask pharmacy customers as they try to determine whether or not the customer is engaged in drug diversion.[164] These points were largely reiterated in the letter the DEA sent each Distributor Defendant on February 7, 2007.

592. The letter the DEA sent Distributor Defendants on December 27, 2007 provided even more specific guidance about their obligation "to inform the DEA of suspicious orders."[165] The letter advised that registrants must perform independent analyses of suspicious orders prior to the sales to determine if diversion appears likely, and 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."[166] According to the December 27, 2007 Letter, monthly reports submitted after orders were already filled and sent to customers would not meet the regulatory requirement, nor would providing daily, weekly, or monthly

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[163] *Id.*

[164] *See also* Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration, *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf.

[165] December 27, 2007 Letter, p. 1.

[166] *Id.*

"excessive purchases" reports.[167]

593. Finally, the letter directed Distributor Defendants to review the final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007), which "specifically discusses your obligation to maintain effective controls against the diversion of controlled substances."[168] The order also provided additional criteria to use when determining whether an order is "suspicious": "Suspicious orders include orders of an 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."[169]

594. The DEA also hosted several distributor conferences to provide Distributor Defendants with "an overview of federal laws and regulations that affect pharmaceutical and chemical distributors, such as recordkeeping, [ARCOS], and suspicious order reporting."[170]

595. Notwithstanding the ample guidance available, Distributor Defendants have failed to maintain adequate suspicious order reporting systems. As a result, and as explained below, Distributor Defendants flooded many communities with opioids, including the communities surrounding Plaintiffs' members, while consistently failing to report or suspend suspicious orders. In doing so, Distributor Defendants fed the sham prescription opioid market that

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[167] *Id.*

[168] *Id.*, p. 2.

[169] *Id*.

[170] *Distributor Conference – May 10 & 11, 2016; Indianapolis, Indiana*, U.S. Drug Enforcement Admin., https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2016/index.html.

Manufacturer Defendants helped create.

596. Distributor Defendants had financial incentives to distribute higher volumes of opioids, and thus refrain from reporting or declining to fill suspicious orders. Drug distributors obtain pharmaceutical products from manufacturers at an established wholesale acquisition cost. They may obtain discounts and rebates from this cost based on market share and volume, such that high volumes of pills may decrease the cost per pill to distributors. Decreased cost per pill in turn allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit.

597. Indeed, as the FTC has recognized, Distributor Defendants "depend on a revenue model that makes money by capitalizing the economies of scale, using both physical efficiencies such as 'just-in-time' deliveries and financial efficiencies, for example, by offering discounts for prompt payment."[171] *See also Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 39 (D.D.C. 1998) (noting that "over the years, [the major pharmaceutical distributors] have acquired other drug wholesale companies and consolidated operations to achieve greater economies of scale"). Because of this revenue model, the more opioids Defendants distribute, the lower their margins and thus, the greater their profits.

598. Manufacturer Defendants paid rebates and/or chargebacks to Distributor Defendants as a way to help them boost opioid sales and better target their marketing efforts. As the leading wholesale distributors, Distributor Defendants had close financial relationships with both manufacturers (including Manufacturer Defendants) and their customers (such as the doctors, clinics, and pharmacies distributing the drugs), for whom Distributor Defendants

[171] Kaiser Foundation, Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain (2005), *available at* http://avalere.com/research/docs/Follow_the_Pill.pdf.

provide a broad range of value-added services that render them uniquely positioned to obtain information about how opioids are being prescribed and used by patients. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock."[172] Distributors use these generic source programs "to combine the purchase volumes of customers and negotiate the costs of goods with manufacturers." In a recent settlement with the DEA, Defendant Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)."[173] This exchange of information opened channels for Distributor Defendants to detect suspicious orders as well.

599. Manufacturer Defendants made use of this data to target their marketing; as discussed above, manufacturers also regularly monitor the activity of doctors and pharmacies, information which they have the ability to share with Distributor Defendants.

600. While Distributor Defendants utilized this information when doing so would be profitable to them, they looked the other way when the information alerted them to potentially suspicious orders. Rather than coordinating with Manufacturing Defendants to curb the misuse and abuse of prescription opioids, Distributor Defendants coordinated with them to fuel the market and undermine enforcement and controls by the government. Efforts to coordinate on this front included lobbying the PCF, discussed above, whose members include Distributor Defendants' trade association, the HDMA.

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[172] *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998)

[173] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 5 (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download.

601. Manufacturer Defendants' aggressive marketing created a market for prescription opioids for chronic pain and overcame barriers to widespread prescribing for these uses; Distributor Defendants' willful ambivalence fueled the widespread prescribing of opioids. By turning a blind eye to red flags and ignoring their obligations to report suspicious orders, Distributor Defendants compounded the harms caused by Manufacturer Defendants by supplying opioids beyond what a legitimate market could bear.

602. Distributor Defendants' gross inadequacies in the performance of their due diligence obligations and their impact on Plaintiffs is underscored by several examples of illegal prescribing and diversion in Illinois.

603. As detailed below, in 2010, the Illinois Department of Financial and Professional Regulation revoked the medical license of Prescriber Defendant Joseph Giacchino, who operated a pill mill in Riverside, Illinois—which is a participating municipality in Plaintiff IRMA's risk pool—after he was discovered to have been prescribing vast quantities of Subsys, an opioid developed exclusively for the treatment of breakthrough pain in cancer patients, and other prescription opioids.

604. From 2014 to 2016, at least three prescribers practicing in the northeast suburbs of Illinois were convicted of crimes in connection with the operation of a pill mill. According to publicly available information (*i.e.*, information readily available to Distributor Defendants) provided by the IDFPR, from 2010 to 2015, at least 88 physicians, nurses, and pharmacy technicians faced some kind of disciplinary action involving drug diversion. None of these disciplinary actions came about through the due-diligence or a suspicious order report from any Distributor Defendant.

605. Additionally, one of Defendant McKesson's distribution facilities was disciplined

by the IDFPR for practicing within the state of Illinois without a license for approximately five years. Defendant Cardinal was also disciplined by the IDFPR for delivering controlled substances to two Illinois pharmacies after the pharmacies' Illinois controlled licenses had expired. These examples, and the conduct of each Distributor Defendant detailed below, support the inference that Distributor Defendants failed to implement and adhere to adequate compliance policies in the distribution centers supplying prescription opioids in Plaintiffs' member communities.

A. McKesson Corporation.

606. McKesson is a wholesale pharmaceutical distributor and one of the largest opioid distributors in the country, supplying pharmacies around the country—including in Plaintiffs' member communities—with prescription opioids like oxycodone and hydrocodone.

607. McKesson operates 28 pharmaceutical distribution centers, including a distribution center in Aurora, Illinois, and elsewhere around the United States.[174]

608. The company holds a third of the market for prescription drugs in the U.S.[175]

609. 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).

610. McKesson is an astoundingly successful company, with revenues of nearly $200 billion in 2016 *alone*.[176] McKesson's opioid business—including sales of products containing oxycodone and hydrocodone—has been an important part of this success, accounting for $2.9

[174] 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/.

[176] S.E.C. Form 10-K, McKesson Corporation (May 22 2017), *available at* http://bit.ly/2ESsjco/.

billion in revenue for the company in 2015.[177] Another estimate places its annual sales revenue from opioids at approximately $4 billion per year, on average.[178]

611. 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 below, Defendant McKesson has repeatedly failed in its duty to diligently investigate and report suspicious orders and customers.

612. As the dominant distributor in the industry, McKesson regularly has senior executives from the company serve on the board of the HDMA. Currently, McKesson's "US Pharma and Specialty Health" President Nick Loporcaro serves on both the executive committee and board of directors of this powerful trade group.[179] Thus, Defendant McKesson is well aware that it has a legal duty to not distribute suspicious orders and to report suspicious orders through the procedures outlined above, and that this duty is essential to protecting public health.[180]

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

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[177] Erika Fry, *supra* note 175.

[178] 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/.

[179] HDA, *Executive Committee*, https://www.healthcaredistribution.org/about/executive-committee (last visited Oct. 14, 2018).

[180] 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* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Oct. 14, 2018).

company's practice of hiring former DEA employees, Defendant 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."[181]

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

615. For example, in 2007, the DEA accused Defendant 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."[182]

616. In May 2008, McKesson and the DEA entered into an Administrative Memorandum of Agreement to settle claims that it had failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in the diversion of millions of doses of controlled substances. [183] McKesson agreed to pay a $13.25 million civil fine.

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[181] 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.

[182] 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/.

[183] See Press Release, "McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications," U.S. Dept. of Justice, (May 2, 2008).

617. After being caught failing to comply with these particular obligations, McKesson made broad promises to change its ways. McKesson agreed to improve its opioid distribution monitoring by—in part—implementing a "Controlled Substance Monitoring Program," a three-tiered system that would flag buyers who exceeded monthly thresholds for opioids. According to an article in *Fortune*, the Controlled Substance Monitoring Program 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.[184]

618. As a result of these agreements, "McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to [the] DEA."[185]

619. According to documents filed in a recent shareholder lawsuit against Defendant 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.

620. Rather than address the problems head on, records show that McKesson's board of directors did not even discuss its compliance system until 2013. And from 2008 to 2013,

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[184] Erika Fry, *supra* note 183.

[185] *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, p. 3, May 2. 2008.

McKesson "supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills, frequently misused products that are part of the current opioid epidemic."[186] For instance, of 1.6 million orders for controlled substances Defendant 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.[187] This instance took place in March 2012, according to a news report in the year following the settlement, four years after Defendant 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).[188]

621. Indeed, from 2008 onwards Defendant 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."[189]

622. In 2012, McKesson caught the attention of the DEA again amid reports from state and local law enforcement agencies that drugs from certain of McKesson's warehouses were being diverted into neighboring communities.[190] McKesson had failed to report to the DEA

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[186] Press Release, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs," U.S. Dept. of Justice Office of Public Affairs, 17 Jan. 2017, https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[187] 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.

[188] Erika Fry, *supra* note 175.

[189] Erika Fry, *supra* note 183.

[190] Bernstein, Lenny & Higham, Scott, *'We feel like our system was hijacked': DEA agents say a huge opioid case ended in a whimper*, Washington Post (Dec. 17, 2017), https://www.washingtonpost.com/investigations/mckesson-dea-opioids-

suspicious orders concomitant to the unusual volume of pills it was pumping into local retail pharmacies with no legitimate reason for such high volume, high frequency orders.

623. This investigation led to the January 17, 2017 announcement that the Department of Justice was fining Defendant McKesson $150 million as part of a settlement over claims Defendant McKesson had 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. It also, for the first time ever in the context of a Controlled Substances Act settlement, required McKesson to engage an independent monitor to assess its compliance with a new, enhanced compliance regime, going forward.

624. According to the DOJ, McKesson was "neither rehabilitated nor deterred by the 2008 [agreement]," did not fully implement or follow its Controlled Substances Monitoring Program, and had continued to fail to report suspicious orders between 2008 and 2012.[191]

625. The 2017 agreement with the DOJ specifically identified McKesson's distribution center in Aurora, Illinois as one of the distribution centers where McKesson "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers."[192]

626. Defendant McKesson was also forced to suspend sales of controlled substances from four of its distribution centers, including its distribution center in Aurora, Illinois.[193]

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fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?noredirect=on&utm_term=.3bf812a21b85

[191] *Id.*

[192] Press Release, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs," *supra* note 187.

[193] *Id.*

627. In an Administrative Memorandum of Agreement entered into between McKesson, the DOJ, and the DEA, McKesson acknowledged that, as documented above, it had not adequately reported suspicious orders of opioids from 2008 to 2013, nor implemented the monitoring and reporting programs it had agreed to in 2008.[194] Specifically:

- "McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA [Controlled Substances Act], and 21 C.F.R. § 1301.74(b);
- "McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP [Controlled Substance Monitoring Program] files maintained for many of its customers, and bypassed suspicious order reporting procedures set for in the McKesson CSMP;"
- "McKesson failed to inform the DEA Field Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers…including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;"
- "McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined in the DEA Letters;"
- "The McKesson 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 by practitioners acting in the course of their professional practice, as required by 21 C.F.R. § 1306.04(a)."[195]

628. Finally, McKesson admitted that "at various times during the Covered Time Period, [McKesson] 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

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[194] *Id*.

[195] Dep't of Justice, Administrative Memorandum of Agreement, at 3-4 (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download; Press Release, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs," *supra* note 187.

consistent with the requirements set for the 2008 MOA." [196]

629. At least part of the reason McKesson's Controlled Substance Monitoring Program failed to adequately flag suspicious orders during this period was 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, McKesson simply ignored the thresholds it set altogether.

630. 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 taking place during this period.[197] Reasonably prudent distributors of Schedule II controlled substances would have anticipated such dangers and protected against it 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' member 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.

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[196] Dep't of Justice, Administrative Memorandum of Agreement, *supra* note 196, at 3.

[197] 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.

631. McKesson did none of these things, or did them with such lack of care and inefficiency as to render them meaningless. As a result, McKesson distributed massive amounts of opioids to pharmacies in Plaintiffs' member communities that it knew (or should have known) were dispensing those opioids pursuant to nonlegitimate prescriptions.

632. McKesson had ample access to sophisticated software systems that allowed it to monitor the inventory and ordering needs of its customers. For example, McKesson regularly engaged third-party data vendors to provide reports detailing prescribing patterns of physicians and analyzing trends in the market, which McKesson used to drive its market share.[198]

633. Put simply, at any given time, McKesson could identify precisely how many opioid pills it delivered to a specific pharmacy. This information allowed McKesson to track and identify instances of overprescribing and alerted McKesson to the problems of abuse and diversion that flowed directly from its distribution patterns. Nonetheless, McKesson's pattern of carelessness continued unabated on for a decade before the Department of Justice stepped in.

B. AmerisourceBergen.

634. AmerisourceBergen is a wholesale distributor of pharmaceuticals, operating 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.

635. The company holds a 30 percent share of the market for prescription drugs in the U.S.[199]

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[198] *Sorrell v. IMS Health Inc*., No. 10-779, 2011 WL 705207, at *467-*471 (Feb. 22, 2011) (A firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product.)

[199] Adam J. Fein, *2016 MDM Market Leaders | Top Pharmaceutical Distributors*, MDM (last visited Oct. 14, 2018), https://www.mdm.com/2016-top-pharmaceuticals-distributors.

636. 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).

637. 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.[200] Indeed, in one year, the company distributed 3.8 million units of hydrocodone to "rogue pharmacies."[201] 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.[202] This did not happen.

638. 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.[203]

639. 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.[204]

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[200] Reuters Staff, *AmerisourceBergen Gets DEA Distribution Halt Order*, Reuters (Apr. 24, 2007), https://www.reuters.com/article/amerisourcebergen-dea/amerisourcebergen-gets-dea-distribution-halt-order-idUSWEN695120070425.

[201] 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.

[202] 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.

[203] 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.

[204] *See e.g.*, Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*,

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.

640. AmerisourceBergen has repeated this conduct in Illinois and in Plaintiffs' member communities, shipping mass quantities of oxycodone and hydrocodone into their villages, towns, and cities without regard for its reasonably foreseeable consequences and in violation of its obligations under Illinois law.

C. Cardinal Health.

641. 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.

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

643. The company holds a 22 percent share of the market for prescription drugs in the U.S.[205]

644. 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

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Charleston Gazette-Mail (Dec. 17, 2016), http://www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses.

[205] Adam J. Fein, *2016 MDM Market Leaders | Top Pharmaceutical Distributors*, MDM (last visited Oct. 14, 2018), https://www.mdm.com/2016-top-pharmaceuticals-distributors.

pharmaceutical division.

645. Cardinal Health is a significant distributor of prescription opioids in the United States and in Plaintiffs' member 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 stores in and around Plaintiffs' member communities.

646. 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.

647. 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.

648. 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.

649. 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.

650. 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.[206]

651. 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."[207]

652. 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."[208]

653. Given the company's sales volume in Plaintiffs' member communities, in Illinois, and around the country, and its history of violations, this executive was either ignorant,

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[206] 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.

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

[208] 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.

misinformed, or simply not telling the truth. Cardinal Health has shipped mass quantities of oxycodone and hydrocodone into Plaintiffs' member villages, towns, and cities without regard for its reasonably foreseeable consequences and in violation of its obligations under Illinois law.

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

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

655. Among these entities is Melrose Park Clinic, Ltd., which has operated under the name Riverside Pain Management since at least January 1, 2013.[209] Hereafter, any operations associated with this corporate entity are referred to as "Melrose Park Clinic."

656. IPBC has shouldered the costs of numerous opioid prescriptions dispensed from Melrose Park Clinic, specifically by Prescriber Defendants Joseph Giacchino and Paul Madison.

A. Defendant Giacchino

657. Defendant Giacchino first received his Illinois medical license in 1974.[210] At or around this time, Giacchino obtained a license to dispense controlled substances in Illinois.

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

659. Giacchino's conduct over the next three decades—and particularly his conduct in the 2000's—has fit a distinct pattern, in which he repeatedly flouted professional standards, state regulations, and the law of Illinois in order to dispense vast quantities of opioids to patients

[209] 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/.

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

throughout Cook County, including to patients covered under IPBC's prescription drug coverage program.

660. In doing so, his conduct has been so brazen and destructive as to earn him the nickname "Dr. Millionpills.'"[211]

661. 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."[212] 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.[213]

662. The IDFPR restored Giacchino's controlled substance license, subject to a two-year probationary period, in June 1998.[214]

663. 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' networks) without performing the basic diligence required of his profession, and without regard for those patients' susceptibility to, or then-ongoing, drug addiction.

664. On April 22, 2010, the IDFPR's Director granted an emergency petition to

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[211] 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.

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

[213] *Id.*

[214] *Id.* ¶ 4.

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' Medical Practice Act and Controlled Substances Act.

665. 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.[215]

666. The ALJ noted that Giacchino's prescribing "such large amounts of controlled substances at each visit was not for a medically accepted therapeutic purpose."[216] 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.[217]

667. 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

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[215] 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.

[216] *Giacchino*, 2013 IL App (1st) 122694-U, ¶ 63.

[217] *Id.* ¶¶ 65–69.

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.[218]

668. As discussed below, this turn of fortune hardly stopped Giacchino's behavior. It merely required a shift in practices in order to continue doing what he had been doing for years: selling vast quantities of opioids in Plaintiffs' communities for his personal enrichment.

B. Defendant Madison

669. 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."

670. 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.

671. 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.

672. Madison's primary method of treating patients for pain, including chronic non-cancer pain, was through the use of prescription opioids.

673. 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.[219] Madison remained president of Melrose Park Clinic until its

[218] *Giacchino*, 2013 IL App (1st) 122694-U, ¶¶ 71–74, 116.

[219] Bob Uphues, *Controversial Ex-Doc Rents Space For Medical Office In Riverside*, *supra* note

involuntary dissolution in 2017.

674. 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.[220]

675. In 2015, the state of Michigan suspended Madison's license to practice medicine.[221] Madison's medical license was ultimately 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.

676. His license remains suspended to this day.[222]

677. In November 2016, Madison was named as an unindicted co-conspirator in a federal lawsuit filed in November 2016 in Massachusetts against Insys Therapeutics, Inc., a pharmaceutical company that manufactures and sells a Schedule II narcotic and fentanyl oral spray product, Subsys. The lawsuit identified Madison as a KOL used by Insys to help promote 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

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210.

[220] 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.

[221] 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/.

[222] Bob Uphues, *Lawyer Wants Out Of Riverside Pain Doc's Case*, Riverside-Brookfield Landmark (Feb. 21, 2017), http://www.rblandmark.com/News/Articles/2-21-2017/Lawyer-wants-out-of-Riverside-pain-doc's-case/; Bob Uphues, *Controversial Ex-Doc Rents Space For Medical Office In Riverside*, *supra* note 210.

who did not specialize in treating cancer-related pain.

678. 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 treating cancer patients.[223] Madison spoke at approximately 46 such events in the Chicago area between November 2012 and June 2015.

679. 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."

680. Indeed, until 2016 Madison was the top Subsys prescriber in Illinois, dispensing as much as 58 percent of all Subsys prescriptions in the state.[224] Of these prescriptions, the attorney general alleged, more than 95 percent were not for the treatment of breakthrough cancer pain.

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

681. 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."[225]

682. Giacchino also said that Defendant Madison would be the doctor treating patients at Melrose Park Clinic's new location. Defendant McMahon was also brought on to work at

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[223] 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.

[224] *Id*.

[225] Bob Uphues, *Controversial Ex-Doc Rents Space For Medical Office In Riverside*, *supra* note 210.

Melrose Park Clinic.

683. 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.

684. The prescriptions Madison issued did not remain in Riverside, but made it as far as 100 miles away.[226] 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.[227]

685. As a consequence of his conduct, Defendant Madison had his medical license suspended in November 2016 for prescribing opioids for non-therapeutic purposes, including through his work at the Melrose Park Clinic.

686. Defendant Madison 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.[228]

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[226] 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/.

[227] 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/.

[228] 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/.

687. 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.

688. With no doctors left to push opioids on the public, Melrose Park Clinic finally closed its doors for good on March 10, 2017.[229] But the damage had already been done.

689. In total, Prescriber Defendants have had a devastating impact on the market for prescription opioids in the Plaintiffs' member communities by dispensing enormous quantities of opioid prescriptions within, and to citizens within, Plaintiffs' communities over the past decade, including to individuals covered by Plaintiffs' benefits programs.

690. 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' communities was not consistent with reasonable clinical practice, and was diverting opioids into the illegal market. 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, Prescriber Defendants undertook no efforts to change their practices. They sold the prescriptions for opioids, took the money, and never looked back, even though the volume of pills they were distributing to individual customers, and as a whole, was suspicious on its face.

691. Prescriber Defendants also knew or should have known that Plaintiffs' member communities (and the State of Illinois at large) have been experiencing an opioid epidemic of

[229] 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/.

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.

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

693. Defendant Madison knowingly or negligently wrote suspicious prescriptions of opioids from January 2013 to March 2017, when the Melrose Park Clinic shut its doors. In addition, Defendant Giacchino knowingly or negligently wrote suspicious prescriptions of opioids, and aided and abetted in doing so, from the time Illinois reinstated his suspended controlled substances license in June until March 2017, when the Melrose Park Clinic shut its doors.

COUNT I
VIOLATIONS OF 815 ILCS 505/2
(Against Manufacturer and Distributor Defendants)

694. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

695. 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.

696. 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 considering whether or not to purchase prescription opioids, as well as the doctors responsible for prescribing them and Plaintiffs, who were responsible for paying for them.

697. 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' networks 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.

698. 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.

699. 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 Defendants' affirmative representations to them, including other adverse effects of opioid use.

700. 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.

701. 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 Plaintiffs to pay out claims for prescription opioids they otherwise would not have paid for—that was the entire point.

702. 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 and burying unfavorable research that would disclose this information to consumers;

deliberately using unbranded marketing materials to evade FDA oversight and rules prohibiting deceptive marketing; and promoting their opioids for off-label uses.

703. This conduct offends the public policy in Illinois. As the legislature has decreed in passing the Illinois Controlled Substances Act, the abuse of prescription drugs causes substantial harm to "the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100; *see also* 745 ILCS 35/2 ("drug addiction [is] among the most serious health problems facing the people of the State of Illinois"). 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.

704. This conduct was also oppressive to Plaintiffs. Plaintiffs put their trust in the physicians in their networks to appropriately convey and balance the risks and benefits of various treatment options for patients covered by Plaintiffs' benefits programs. Physicians, in turn, are inclined to trust the advice of KOLs, front groups, and other seemingly independent sources of objective medical information. Plaintiffs also put their trust in medical management vendors and third-party health care providers to review claims for medical necessity, and these groups likewise put their trust in seemingly independent sources of objective medical information to determine the appropriate standard of care. 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 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.

705. As such, Manufacturing Defendants have engaged in fraudulent, deceptive,

unlawful, and unfair business practices in violation of Section 2 the ICFA.

706. Moreover, Distributor Defendants are in the position to implement effective business practices to guard against diversion of the highly-addictive opioid products it sells and distributes. Instead, they profited off the opioid epidemic by ignoring anti-diversion laws and selling 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.

707. Distributor Defendants' acts in violation of law are also business practices that constitute independent violations of the ICFA. Defendants' unlawful, unfair, and fraudulent business practices include the filling of suspicious or invalid orders for prescription opioids at both the wholesale and retail level; 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 suspicious orders and filling them anyway.

708. These practices are fraudulent because Distributor Defendants had a duty to disclose suspicious orders to the DEA. Distributor Defendants also had a common law duty to disclose suspicious orders because the public—namely, local law enforcement and insurance providers—relied upon Distributor Defendants' disclosures to investigate potential diversion, drug abuse, and drug misuse. Defendant McKesson, for its part, misrepresented its compliance with its legal duties under state and federal law and sought to convince the public that its legal duties had been satisfied through its public assurances that it was working to improve its substance monitoring program to help identify suspicious orders, when instead, it was actively

evading those duties. These affirmative actions also prevented Plaintiffs from discovering the existence of and filing its claims any earlier.

709. As such, Distributor Defendants have engaged in fraudulent, deceptive, unlawful, and unfair business practices in violation of Section 2 the ICFA.

710. Defendants' conduct has grievously injured Plaintiffs, causing them to spend money on opioid prescriptions, opioid-related medical treatment, and other workers' compensation benefits that they otherwise would not have, but for Defendants' willing violations of public policy and oppressive behavior.

711. 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.

712. Because Manufacturer Defendants' marketing caused doctors and other health care providers to prescribe and Plaintiffs to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Manufacturer Defendants caused and are responsible for those costs and claims, as well.

713. No public policy justifies Defendants' misconduct, including the Defendants' decades'-long misinformation campaign, which made it wholly unreasonable to expect that Plaintiffs could have avoided their injuries.

714. 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 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.

715. 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 II
VIOLATIONS OF 815 ILCS 505/2
(Against Front Group Defendants)

716. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

717. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction, in disseminating misleading information regarding the appropriateness of their opioids for certain conditions, and in falsely portraying their statements as those of independent, unbiased third-parties, Front Group Defendants AAPM, AGS, and APS have engaged in misrepresentations, deception, and knowing omissions of material fact.

718. These material misrepresentations and omissions include, but are not limited to, those set forth in First Cause of Action, above.

719. As a direct and proximate result of these violations of the IFCA, Plaintiffs have suffered and continue to face injury and damage, including by spending money on opioid prescriptions, opioid-related medical treatment, and other workers' compensation benefits.

720. Plaintiffs respectfully request that this Court enter an order (a) awarding judgment in their favor and against Front Group Defendants; (b) enjoining Front Group Defendants from performing or proposing to perform any acts in violation of the ICFA; and (c) awarding Plaintiffs

such other, further, and different relief as the Court may deem just.

COUNT III
FRAUDULENT MISREPRESENTATION
(Against Manufacturer Defendants)

721. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

722. 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, 342-43 (2008).

723. Manufacturer Defendants' practices, as described in the Complaint, constitute fraudulent misrepresentation because the practices were intended to deceive doctors, consumers, other health care providers in Plaintiffs' network, and Plaintiffs, and occurred in connection with the sale or advertisement of merchandise: that is, prescription opioids.

724. At all times relevant to the Complaint, Manufacturer Defendants, directly and 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.

725. 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.

726. 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 Manufacturer 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.

727. 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.

728. All of this conduct, separately and collectively, was intended to deceive Plaintiffs' member communities who used or paid for opioids for chronic pain; prescribers who prescribed opioids for chronic non-cancer pain; and Plaintiffs, who covered the purchase of opioids for chronic non-cancer pain.

729. 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 prescription drugs and opioid-related medical treatments, as well as through coverage for excess disability leave which would not have occurred but for the employees' use of prescription opioids.

730. Because Manufacturer Defendants' marketing caused doctors and other health

care providers to prescribe and Plaintiffs to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Manufacturer Defendants caused and are responsible for those costs and claims, as well.

731. 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.

732. Plaintiffs also request this Court enter an order awarding declaratory relief by declaring that Manufacturer Defendants' misrepresentations described herein were fraudulent and requiring Manufacturer Defendants to cease making such fraudulent misrepresentations in the future.

COUNT IV
INSURANCE FRAUD
(Against Manufacturer Defendants)

733. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

734. 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."

735. 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."

736. 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, and—through their deception—obtained the property of Plaintiffs in payment for those false claims.

737. Manufacturer Defendants' scheme caused prescribers to write prescriptions for opioids to treat chronic pain that were presented to Plaintiffs for payment. Therefore, each claim for reimbursement paid by Plaintiffs for chronic opioid therapy is the direct result of Manufacturer Defendant's 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.

738. Plaintiffs only cover the cost of medical services and prescription drugs that are medically necessary and reasonably required. Doctors, pharmacists, other health care providers in Plaintiffs' networks (and agents thereof) 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.

739. Manufacturer Defendants caused doctors and pharmacies to submit, and Plaintiffs to pay claims that were false by: (a) causing doctors to write prescriptions for chronic opioid therapy based on deceptive representations regarding the risks, benefits, and superiority of those drugs; (b) causing doctors to certify that these prescriptions and associated services were medically necessary and/or reasonably required; and (c) distorting the standard of care for treatment of chronic pain so that doctors would feel not only that it was appropriate, but required,

that they prescribe opioids long-term to treat chronic pain. Each—or any—of these factors made claims to Plaintiffs for chronic opioid therapy false.

740. These misrepresentations were material because, had Plaintiffs known of the false statements disseminated by Manufacturer Defendants, Plaintiffs would have refused to pay for those opioid prescriptions and the attendant costs related to the patients' prescription opioid use.

741. 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.

742. 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.

743. Plaintiffs respectfully request that this Court enter an order awarding judgment in its 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.

744. Plaintiffs also request this Court enter an order awarding declaratory relief by declaring that Manufacturer Defendants' misrepresentations described herein were fraudulent and requiring Manufacturer Defendants to cease making such fraudulent misrepresentations in the future.

COUNT V
NEGLIGENCE
(Against Distributor Defendants)

745. Plaintiffs incorporate by reference the preceding paragraphs of this Complaint as if fully set forth herein.

746. 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. 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 (2006).

747. Distributor Defendants have a duty to exercise reasonable care in distributing highly dangerous opioid drugs in Plaintiffs' communities. This includes a duty not to cause foreseeable harm to others.

748. In addition, Distributor Defendants have engaged in a course of conduct that created a foreseeable risk of injury, and thus had and still have a duty to protect others from such injury. Like every person, Distributor Defendants owe a duty of ordinary care to all others to guard against injuries which naturally flow as reasonably probable and foreseeable consequences of their actions.

749. Distributor Defendants are part of a limited class of registrants authorized to legally market, sell, and distribute controlled substances, which places them in a position of great trust and responsibility vis-à-vis Plaintiffs. Their duty cannot be delegated.

750. In addition, 21 U.S.C. § 801 et seq.; 21 C.F.R. § 1301.74; 21 C.F.R. § 205; the ICSA, including 720 ILCS 570/303; and Ill. Admin. Code tit. 68, § 1510.50, are public safety laws. Each Distributor Defendant had a duty under, *inter alia*, 21 U.S.C. § 801 et seq., 21 C.F.R. § 1301.74, 720 ILCS 570/303, and Ill. Admin. Code tit. 68, § 1510.50, to maintain effective controls against diversion and misuse of prescription opioids, to report suspicious orders of opioids, and not to fill suspicious orders unless and until due diligence had eliminated the basis for its suspicion.

751. 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.

752. Distributor Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the misuse of prescription opioids when, in reality, they failed to satisfy even their minimum, legally-required obligations to report suspicious orders. Distributor Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent opioid abuse and misuse.

753. Distributor Defendants' breach of its duties fueled widespread opioid prescribing. Indeed, the very purpose of Distributor Defendants' duties was to prevent the abuse and misuse of dangerous narcotics, making the causal connection between Distributor Defendants' breach and the ensuing harms to Plaintiffs wholly foreseeable.

754. Distributor Defendants' conduct caused opioids to become widely available, widely prescribed, and widely used, and their actions were, at the very least, a substantial factor in the widespread abuse of opioids. Without Distributor Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the costs borne by Plaintiffs would have been averted or much less severe.

755. Plaintiffs were injured as the factual and proximate result of Distributor Defendants' conduct, costing Plaintiffs millions of dollars in additional opioid-related expenses. Such an injury was entirely foreseeable because reasonably prudent distributors would know that failing to maintain effective controls against the misuse of a highly addictive narcotic would lead to overprescription (and overpayment by payors like Plaintiffs), as well as the attendant costs of opioid addiction.

756. As a result, Distributor Defendants are liable for negligence.

757. Plaintiffs seek all legal and equitable relief allowed by law, including injunctive relief requiring Distributor Defendants to cease their negligent activity, restitution to Plaintiffs for the damages caused by Distributor Defendants' negligence, disgorgement of Distributor

Defendants' profits caused by Distributor Defendants' negligence, entering a monetary judgment in favor of Plaintiffs and against Distributor Defendants for compensatory and punitive damages, and all other damages allowed by law.

COUNT VI
PUBLIC NUISANCE
(Against All Defendants)

758. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

759. 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. (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.*

760. The individuals covered by Plaintiffs 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.

761. As described herein, Defendants have created a continuing public nuisance in Plaintiffs' member communities through their conduct by creating a medical consensus for prescribing patterns that have adverse effects on patient welfare, including: Manufacturer Defendants' widespread campaign to aggressively and deceptively market prescription opioids beyond their approved uses; and Distributor Defendants' intentionally and/or recklessly distributing and selling prescription opioids that they knew, or reasonably should have known,

were being overprescribed or misused, while illegally failing to put appropriate controls in place. By causing what has been (and is) commonly referred to as a "crisis" or "epidemic" stemming from the misuse and abuse of opioid prescriptions, Defendants have individually and collectively created an unreasonable public nuisance nationwide, including in Plaintiffs' member communities.

762. 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 opioid addiction-related medical treatment.

763. At all times relevant to this action, Defendants were in control of the "instrumentality" of the nuisance – Manufacturing Defendants and Front Group Defendants controlled the creation and maintenance of the demand for prescription opioids and the process of marketing (including the misleading representations they conveyed through branded and unbranded marketing and the instrumentalities used to disseminate their misleading messages); Distributor Defendants the protocols for determining whether suspicious orders would be monitored, halted, and reported; and Prescriber Defendants controlled the issuance of bogus opioid prescriptions through the Melrose Park Clinic.

764. It was unreasonable for Distributor Defendants to fail to design and operate a system that would disclose the existence of suspicious orders and/or fail to report and halt suspicious orders, as required by the ICSA, 720 ILCS 570 (which also incorporates the CSA's obligations) and the CSA, 21 C.F.R. §1301.74(b). It was also unreasonable for Manufacturing Defendants to misrepresent the risks, benefits, or superiority of opioids; the responsibility of a drug's manufacturers to ensure that its promotional activities do not violate consumer protection

laws exists independent of any FDA approval.

765. Prescription opioids are specifically known to Defendants to be dangerous because, *inter alia*, these drugs are regulated as controlled substances under federal and state law as a result of their high potential for abuse and addiction. Defendants' own surveillance (or data they purchased and/or collected) demonstrated the widening toll of opioid addiction, overdose, hospitalizations, and fatalities, and alerted them to the likelihood of the epidemic that ensued.

766. Each Defendant's actions were a material element (at the very least) in misleading prescribers, patients, and payors about the risks and benefits of opioids and, as a result, in opioids becoming widely demanded, widely available, and widely used in claimants in Plaintiffs' member communities, bringing the injuries to Plaintiffs described above.

767. Moreover, in light of Manufacturer Defendants' deceptive marketing campaign and Distributor Defendants' misleading representations about their compliance with their above-described duties, Plaintiffs were unaware of, and could not reasonably know or have learned through reasonable diligence, that they were exposed to the risks described herein. For these same reasons, they could not reasonably know or have learned through reasonable diligence that Defendants were responsible for creating, perpetuating, and maintaining the opioid epidemic.

768. 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.

769. 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 VII
CIVIL CONSPIRACY
(Against Defendants Cephalon, Endo, Janssen, Purdue, and Front Group Defendants)

770. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

771. 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.

772. Defendants Cephalon, Endo, Janssen, and Purdue each conspired with Front Group Defendants, various KOLs, and other front groups to commit unlawful acts or lawful acts in an unlawful manner. Defendants Cephalon, Endo, Janssen, and Purdue and the various KOLs and front groups with which each of them was allied (including Front Group Defendants APS, AAPM, and AGS), knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote the use of opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants Cephalon, Endo, Janssen, and Purdue enlisted various KOLs and front groups to make and disseminate these statements in furtherance of their common strategy to increase opioid sales, and Defendants Cephalon, Endo, Janssen, and Purdue—along with the KOLs and front groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

773. By engaging in the conduct described in this Complaint, Defendant Cephalon agreed with front groups FSMB and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with FSMB and APF, Cephalon provided support for FSMB's and APF's deceptive statements promoting opioids and FSMB and APF used that support to more broadly disseminate deceptive messaging promoting opioids,

which would benefit Cephalon's drugs. *Responsible Opioid Prescribing* (Cephalon and FSMB) and *Treatment Options: A Guide for People Living with Pain* (Cephalon and APF) are publications that contained a number of deceptive statements about opioids as outlined above. They are products of these conspiracies, and the collaboration between Cephalon and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

774. By engaging in the conduct described in this Complaint, Defendant Endo agreed with front groups APF, NIPC, AGS and FSMB that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, NIPC, AGS and FSMB, Endo provided support for APF, NIPC, AGS and FSMB's deceptive statements promoting opioids and APF, NIPC, AGS and FSMB used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Endo's drugs. *Persistent Pain in the Older Adult* (Endo, APF, and NIPC), *Persistent Pain in the Older Patient* (Endo, APF, and NIPC), *Painknowledge.com* (Endo, APF, and NIPC), *Exit Wounds* (Endo and APF); *Pharmacological Management of Persistent Pain in Older Persons* (Endo and AGS), and *Responsible Opioid Prescribing* (Endo and FSMB) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined above. They are products of these conspiracies, and the collaboration between Endo and each of these entities in creating and disseminating these publications, CMEs, and websites is further evidence of each conspiracy's existence.

775. By engaging in the conduct described in this Complaint, Defendant Janssen agreed with Front Group Defendants AAPM, AGS, and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with

AAPM, AGS, and APF, Janssen provided support for AAPM, AGS, and APF's deceptive statements promoting opioids and Conrad & Associates LLC, Medical Writer X, AAPM, AGS, and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Janssen's drugs. *Finding Relief: Pain Management for Older Adults* (Janssen, AAPM, and AGS), a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Janssen and AGS), the *Let's Talk Pain* website (Janssen and APF), and *Exit Wounds* (Janssen and APF) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined above. They are products of these conspiracies and the collaboration between Janssen and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

776. By engaging in the conduct described in this Complaint, Defendant Purdue (alongside others) agreed with front groups APF, FSMB, and AGS that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, FSMB, and AGS, Purdue provided support for APF, FSMB, and AGS's deceptive statements promoting opioids and APF, FSMB, and AGS used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Purdue's drugs. The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit Wounds* (Purdue and APF),[230] *Responsible Opioid Prescribing* (Purdue and FSMB), and a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS) are publications, CMEs, and websites that contained a

[230] Purdue's collaboration with APF through APF's "Corporate Roundtable" and Purdue and APF's active collaboration in running PCF constitute additional evidence of the conspiracy between Purdue and APF to deceptively promote opioids.

number of deceptive statements about opioids as outlined above. They are products of these conspiracies, and the collaboration between Purdue and each of these entities in creating and disseminating these publications, CMEs, and websites is further evidence of each conspiracy's existence.

777. Each of the participants to the conspiracies outlined above was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. These Manufacturer Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to patients and prescribers in Plaintiffs' networks in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

778. As outlined above, Defendants Cephalon, Endo, Janssen, and Purdue played an active role in determining the substance of the misleading messages issued by KOLs and front groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants Cephalon, Endo, Janssen, and Purdue further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was an unrelenting stream of misleading information about the risks, benefits, and superiority of using opioids to treat chronic pain from sources that Defendants Cephalon, Endo, Janssen, and Purdue knew were trusted by prescribers. Defendants Cephalon, Endo, Janssen, and Purdue exercised direct editorial control over most of these statements. However, even if Defendants Cephalon, Endo, Janssen, and Purdue did not directly disseminate or control the content of these misleading

statements, they are liable for conspiring with the third parties who did.

779. Defendants Cephalon, Endo, Janssen, and Purdue participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

- violating, aiding and abetting in the violation, or causing the violation of 720 ILCS § 5/17-10.5;
- violating 21 U.S.C. § 331(a);
- violating 410 ILCS 620/3;
- committing common law unjust enrichment; and
- creating a public nuisance.

780. Because of these unlawful acts, Plaintiffs have been damaged and continue to be damaged by paying for the costs of opioid prescriptions for chronic pain and have suffered additional damages by paying for the costs of providing and using opioids long-term to treat chronic pain.

781. Because Defendants Cephalon, Endo, Janssen, and Purdue's marketing caused doctors and other health care providers to prescribe and Plaintiffs to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendants Cephalon, Endo, Janssen, and Purdue caused and are responsible for those costs and claims, as well.

782. Plaintiffs respectfully request this Court enter an order awarding judgment in their favor to compensate them for injuries sustained as a result of Defendants' misconduct, for restitution of any money acquired as a result thereof, and awarding such other relief as this Court may deem just.

783. Plaintiffs also request this Court enter an order awarding declaratory relief by declaring that Defendants' (Cephalon, Endo, Janssen, and Purdue's) activities constituted a civil conspiracy, enjoining Defendants from engaging in any further activities constituting civil conspiracy, providing injunctive relief requiring Defendants to abate any harm caused by their civil conspiracy.

COUNT VIII
CIVIL CONSPIRACY
(Against Prescriber Defendants)

784. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

785. 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.

786. 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.

787. 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 Madison's medical license), and prior instances of precisely the same conduct engaged in by the Melrose Park Clinic's "administrator," Defendant Giacchino.

788. 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 Defendant 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); *see also* 720 ILCS 570/312 (requirements for dispensing controlled substances).

789. 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.

790. 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.

791. 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.

792. 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
UNJUST ENRICHMENT
(Against Manufacturer Defendants, Distributor Defendants, and Prescriber Defendants)

793. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

794. 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 (1995) (internal quotations and citations omitted).

795. 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.

796. Defendants' manufacturing, marketing, 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.

797. Plaintiffs, on their own and on behalf of their members, conferred benefits on each Defendant, including payments for opioids manufactured by Defendants for sale. These benefits were known to and accepted by each 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 Defendants that contributed to and caused the opioid epidemic in Plaintiffs' member communities. Thus, Defendants have been unjustly enriched by their deceptive practices.

798. The unprecedented opioid epidemic has cost Plaintiffs hundreds of thousands of dollars in health insurance and workers' compensation claims. 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.

799. It would be inequitable under these circumstances for Defendants to be allowed to retain these benefits without compensating Plaintiffs for their value. The enrichment Defendants experienced was without justification and Plaintiffs lack a remedy provided by law.

800. As such, Plaintiffs respectfully request 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests 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 Distributor Defendants have acted negligently;

D. Directing Distributor 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 Manufacturer, Distributer and Front Group Defendants have engaged in unlawful, fraudulent, and deceptive acts in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act;

J. Directing Manufacturer, Distributer and Front Group 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 Manufacturer, Distributer and Prescriber Defendants have been unjustly enriched by their conduct;

L. Directing Manufacturer, Distributer and Prescriber Defendants to pay restitution of all benefits and disgorge all profits unjustly retained to Plaintiffs;

M. Declaring that Defendants Cephalon, Endo, Jannsen, Purdue, Front Group Defendants, and Prescriber Defendants have engaged in an unlawful civil conspiracy;

N. Directing Defendants Cephalon, Endo, Jannsen, Purdue, and Front Group Defendants, and Prescriber Defendants to pay all damages caused by their civil conspiracy to Plaintiffs;

O. Awarding treble and punitive damages as appropriate;

P. Awarding injunctive relief as necessary to protect the interests of Plaintiffs;

Q. Awarding Plaintiffs their reasonable litigation expenses and attorneys' fees;

R. Awarding Plaintiffs pre- and post-judgment interest to the extent allowable; and

S. 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,

INTERGOVERNMENTAL RISK MANAGEMENT AGENCY and INTERGOVERNMENTAL PERSONNEL BENEFIT COOPERATIVE,

Dated: October 15, 2018

By: /s/ Benjamin H. Richman
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