IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY
COORDINATED PROCEEDINGS

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COMMONWEALTH OF PENNSYLVANIA,
acting by and through Philadelphia District
Attorney Lawrence S. Krasner,
Office of the District Attorney
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Philadelphia, PA 19107,

Plaintiff,

v.

PURDUE PHARMA L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901,

PURDUE PHARMA INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901,

THE PURDUE FREDERICK COMPANY, INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901,

ALLERGAN FINANCE, LLC
c/o The Corporation Trust Company of Nevada
701 South Carson Street, Suite 200
Carson City, NV 89701,

CEPHALON, INC.
1090 Horsham Road
North Wales, PA 19454,

TEVA PHARMACEUTICALS USA, INC.
1090 Horsham Road
North Wales, PA 19454,

ENDO HEALTH SOLUTIONS, INC.
1400 Atwater Drive
Malvern, PA 19355,

COURT OF COMMON PLEAS
DELAWARE COUNTY, PA
CIVIL ACTION - LAW
NO.: 2017-008095

COORDINATED PROCEEDINGS

AMENDED COMPLAINT

ENDO PHARMACEUTICALS, INC.
1400 Atwater Drive
Malvern, PA 19355,

JANSSEN PHARMACEUTICALS, INC.
1125 Trenton Harbourton Road
Titusville, NJ 08560-0200,

JOHNSON & JOHNSON
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933,

AMERISOURCE BERGEN DRUG CORP.
227 Washington Street
Conshohocken, PA 19428,

CARDINAL HEALTH, INC.
7000 Cardinal Place
Dublin, OH 43017

and

MCKESSON CORP.
One Post Street
San Francisco, CA 94104,

Defendants.

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AMENDED COMPLAINT

Plaintiff Commonwealth of Pennsylvania (the "Commonwealth"), acting by and through Philadelphia District Attorney Lawrence S. Krasner ("District Attorney"), brings this public enforcement action against the Defendant manufacturers of prescription opioid drugs pursuant to the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-1-201, *et seq.* ("UTPCPL" or "Statute"). In support of this action, the Commonwealth alleges as follows:

INTRODUCTION

1. Fueled by dangerous prescription opioid drugs, the City of Philadelphia (the "City" or "Philadelphia") — like many other cities, counties and states across the country — is now engulfed in an opioid epidemic which has led to a public health and safety crisis of an unprecedented and disastrous nature. The current epidemic in the City is directly attributable to the commercial activities of the Defendant manufacturers and their false, deceptive and improper marketing and promotion of prescription opioids for medical use nationally, regionally and in Philadelphia, in violation of the UTPCPL.

2. The Philadelphia District Attorney, in the name of the Commonwealth, brings this action to hold Defendants accountable under the UTPCPL for their role in creating and perpetuating the opioid epidemic in the City and seeks injunctive relief against the Defendants and, through the restoration and/or restitution remedy in the Statute, disgorgement of the revenues acquired by the Defendants as a result of their violations of the Statute and compensation for the losses of the City and other affected persons in interest within the City attributable to those violations, including, *inter alia*, the addiction treatment and prescriber education necessary to abate the epidemic.

3. Prescription opioid drugs manufactured and distributed by the Defendants –

including their brand-name drugs like Oxycontin, Kadian, Fentora, Opana and Duragesic – are powerful narcotic painkillers. Opioids are, and at all times relevant to this action were, dangerous and have significant and severe adverse side effects on users. While they have a proper medical use, if prescribed responsibly, to treat *short-term* acute pain (such as pain associated with medical surgical procedures, accidents or other medical conditions causing short-term pain) or for end-of-life care, Defendants marketed, promoted, sold, and distributed prescription opioids for *long-term* daily use to treat chronic pain. The overwhelming weight of medical and scientific opinion is and has been that prescription opioids should rarely be used for long-term treatment of chronic pain.

4. Beginning in the mid-1990s, the Defendants, individually and collectively, engaged in massive, systematic false and deceptive marketing aggressively promoting the prescription and use of prescription opioids to treat chronic pain. The Defendants falsely and deceptively marketed both their own branded drugs and the entire therapeutic class of prescription opioids as safe and effective for common forms of chronic pain. Defendants' false and deceptive marketing, individually and collectively, succeeded in significantly modifying the prescribing practices of physicians around the country and in the Philadelphia area with respect to opioids, thereby dramatically increasing the legal prescription and use of opioids in the City, regionally and nationally.

5. Prior to the Defendants' false and deceptive marketing of opioids to doctors in Philadelphia and nationally, the medical profession considered opioids to be dangerous and to have serious adverse side effects, including addiction and increased risk of fatal and non-fatal overdoses. Medical practitioners also recognized that the risk of opioid addiction was considerable for any type of user and that opioid addiction, once it has taken hold, is impossible

to cure and difficult to treat. Prior to Defendants' false and deceptive marketing to influence doctors, third-party payors and others to purchase, or reimburse the purchases of, the drugs, the medical profession held the view that the prescription and medical use of opioids should be cautious and limited.

6. In connection with their false and deceptive marketing, Defendants spent tens of millions of dollars promoting prescription opioids and falsely denied or trivialized the risks of prescription opioids, while overstating the benefits of using them to treat chronic pain. As to these risks and purported benefits, Defendants falsely and deceptively: (1) downplayed the serious risk of addiction; (2) misrepresented that opioids improve patients' function and quality of life or are efficacious for chronic pain; (3) promoted the concept of "pseudoaddiction," which posited that medical symptoms of addiction were not signs of addiction and should be treated with higher and higher doses of opioids; (4) falsely claimed that opioid addiction could be easily managed; (5) falsely claimed that withdrawal symptoms could be easily addressed; and (6) denied the risks of subjecting patients to higher opioid dosages. At the same time, Defendants touted the ostensible benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientific evidence to support Defendants' claims.

7. Defendants' false and deceptive marketing practices were specifically designed to reverse both the popular and medical understanding that opioids were not appropriate to treat chronic pain. Defendants disseminated their promotional messages directly to physicians through their massive sales efforts involving sales calls by armies of sales representatives and the dissemination of written marketing materials and through speaker groups led by physicians whom Defendants recruited to support these marketing messages. Defendants also worked

through third parties they controlled by: (1) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (2) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint sources that doctors and patients relied on for ostensibly "neutral" independent medical guidance, such as treatment guidelines, continuing medical education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known – that opioids were addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* prescription opioids.

8. After a comprehensive review of the increased use of prescription opioids for medical purposes and its ill effects during the last 20 years, public health authorities and medical researchers have reaffirmed and acknowledged that there never was satisfactory scientific evidence, during the period when Defendants engaged in the widespread promotion, marketing and sale of prescription opioids for long-term daily use, to establish that they were effective in treating chronic pain. They also have concluded that long-term daily use of prescription opioids was unsafe and exposed patients to dangerous, unacceptable risks of addiction, fatal and non-fatal overdoses and other serious adverse health conditions and that such risks significantly and dangerously increased with the increased use of prescription opioids. In this light, Defendants' activities in aggressively marketing, promoting, distributing, and selling prescription opioids as a treatment for chronic pain were medically and scientifically unfounded, false, deceptive, ethically inexcusable, and unlawful.

9. The opioid epidemic currently plaguing the City and its deleterious impact on public health and safety have created overlapping crises for the City, its residents and the Philadelphia community as a whole and has adversely affected public and private health plans and third-party payors of prescription drug benefits of these health plans and the City and its agencies:

a. Opioid addiction and the adverse health consequences of prescription opioid use have exacted a grim toll of human suffering on users and their families. As a consequence, the legal purchase and use of prescription opioids have placed an enormous burden on public and private health plans in the City and on third-party payors of prescription drug benefits of these plans to defray the costs of the prescriptions and treatment of the adverse side effects of prescription opioids; and

b. The opioid crisis – with its attendant increase in crime and family and social dysfunction which tear at the social fabric of the City – is also responsible for a sharp deterioration of public safety, order, economic productivity and the quality of life in the City. As a consequence, the City and its agencies, which are in the front lines of attempting to cope with and contain the epidemic and ensuing adverse impacts on public health and safety, have incurred large, burdensome, unnecessary and avoidable costs in the discharge of their duties.

10. Defendants' false and deceptive conduct, which has precipitated and perpetuated the opioid epidemic in the City, has violated and continues to violate the UTPCPL.

11. To redress and punish Defendants' violations of the UTPCPL, the Commonwealth seeks an order from the Court enjoining Defendants from further false and deceptive marketing activities in the City regarding the use of prescription opioids for chronic pain and/or correctly to inform the medical community and the public of the true risks of long-

term opioid prescription opioid use.

12. The Commonwealth also seeks a judgment requiring Defendants to pay the maximum civil penalties available for their violations of the UTPCPL and, by way of restoration and/or restitution, to disgorge all monies acquired or retained by Defendants as a result of their violations in Philadelphia.

13. The Commonwealth also specifically seeks restoration and/or restitution from Defendants to the City of Philadelphia and other injured persons in interest in or doing business in the City, including any health plans, third-party payors or administrators of prescription drug benefits in the City who paid opioid-related claims, of the monies paid for purchases of opioid prescriptions, treatment of opioid addiction or abuse or related diseases attributable to prescription opioids, and other costs and damages that Defendants' violations of the law caused and contributed to.

14. The Commonwealth also seeks restoration and/or restitution relief requiring Defendants to pay to the City and the DA its expenditures for (1) increased City services associated with addiction, fatal and non-fatal overdoses and other adverse health and public safety conditions attributable to prescription opioids manufactured and distributed by Defendants, including the increased emergency response costs, hospitalization, treatment, and other costs; (2) any other monies lost or expenses incurred by the City and the DA as a result of Defendants' violations of the UTPCPL and (3) all additional legal or equitable relief authorized by law.

JURISDICTION AND VENUE

15. This Court has jurisdiction over this action pursuant to 42 P.S. § 931(a). The amount in controversy exceeds $50,000, exclusive of interest and costs, which is the jurisdictional amount below which a compulsory arbitration referral pursuant to 42 P.S. § 7361(b) would be required.

16. Venue is proper in Philadelphia County pursuant to 42 P. S. § 931(c), Pa. R.C.P. 1006(b) and (c)(1), and Pa. R.C.P. 2179(a).

17. This action is not removable to federal court. Among other things, there is insufficient diversity for removal. The Commonwealth is not considered a party for purposes of diversity of citizenship jurisdiction in any event. Further, the claims alleged in the Amended Complaint do not permit federal question jurisdiction to be exercised as the claims do not arise directly or indirectly under the Constitution, laws, or treaties of the United States.

PARTIES

I. Plaintiff

18. Plaintiff is the Commonwealth of Pennsylvania, acting by and through the Philadelphia District Attorney, pursuant to the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-1 – 201-9.3.

19. The District Attorney is expressly authorized to bring this action in the name of the Commonwealth under the UTPCPL whenever the District Attorney has reason to believe that any person is using or is about to use any method, act or practice declared by the UTPCPL to be unlawful, and that such proceedings would be in the public interest. 73 P.S. § 201-4.

20. Based on the allegations herein, the District Attorney has reason to believe that Defendants are using or are about to use methods, acts or practices declared by the UTPCPL to be unlawful and that bringing this action is in the public interest.

II. Defendants

A. The Manufacturer Defendants

21. Defendant Purdue Pharma L.P. ("PPL") is a privately held limited partnership organized under the laws of Delaware, with its principal place of business in Stamford, Connecticut.

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

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

24. At all times material hereto, Defendants PPL, PPI and PFC (collectively, "Purdue") promoted, marketed, and sold opioids nationally and in Philadelphia, including but not limited to the following:

Table 1. Purdue Opioids

Drug Name	Chemical Name	Schedule
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

25. More than half of Purdue's revenue comes from opioids.[1]

26. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for

[1] Esme Deprez, The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry, Bloomberg Businessweek (Oct. 5, 2017), https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.

analgesic drugs (*i.e.*, painkillers).

27. Purdue and its top executives pleaded guilty in 2007 to criminal charges in connection with Purdue's deceptive OxyContin marketing practices, as discussed herein.

28. Defendant Allergan Finance, LLC is a privately held Nevada corporation with its principal place of business in Parsippany, New Jersey. Defendant Allergan Finance, LLC was formerly known as Actavis, Inc., which in turn was formerly known as Watson Pharmaceuticals, Inc. Defendant Allergan Finance, LLC acquired Warner Chilcott plc in 2013. Defendant Allergan Finance, LLC is a wholly-owned subsidiary of Allergan plc, which is incorporated in Ireland with its principal place of business in Dublin, Ireland.

29. Defendant Allergan Finance, LLC and its predecessors and/or combined entities, including but not limited to Actavis, Inc., Watson Pharmaceuticals, Inc., and Warner Chilcott plc (collectively referred to herein as "Allergan/Actavis") promoted, marketed, and sold both brand name and generic versions of opioids nationally and in Philadelphia, including but not limited to the following:

Table 2. Allergan/Actavis Opioids

Drug Name	Chemical Name	Schedule
Kadian	Morphine sulfate extended release	Schedule II
Norco	Hydrocodone bitartrate and acetaminophen	Schedule II
Generic Duragesic	Fentanyl	Schedule II
Generic Kadian	Morphine sulfate extended release	Schedule II
Generic Opana	Oxymorphone hydrochloride	Schedule II

30. Defendant Cephalon, Inc. is a privately held Delaware corporation with its principal place of business in North Wales, Pennsylvania. In 2011, Cephalon, Inc. was acquired by Teva Pharmaceutical Industries, Ltd., an Israeli corporation. Cephalon, Inc. is now a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd.

31. Defendant Teva Pharmaceuticals USA, Inc. is a privately held Delaware corporation, with its principal place of business in North Wales, Pennsylvania. Teva Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd., an Israeli corporation. Defendant Teva Pharmaceuticals USA, Inc. specializes in the manufacturing and marketing of generic drugs, including opioids.

32. At all times material hereto, Defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, "Cephalon") promoted, marketed, and sold both brand name and generic versions of opioids nationally and in Philadelphia, including but not limited to the following:

Table 3. Cephalon Opioids

Drug Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II
Generic oxycodone	Oxycodone hydrochloride	Schedule II

33. Defendant Endo Health Solutions Inc. ("Endo Health") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health is a wholly owned subsidiary of Endo International plc, which is an Ireland-domiciled company.

34. Defendant Endo Pharmaceuticals, Inc. ("Endo Pharmaceuticals") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals is a wholly owned subsidiary of Defendant Endo Health.

35. At all times material hereto, Defendants Endo Health and Endo Pharmaceuticals (collectively, "Endo") promoted, marketed, and sold both brand name and generic versions of opioids nationally and in Philadelphia, including but not limited to the following:

Table 4. Endo Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
Zydone	Hydrocodone bitartrate and acetaminophen	Schedule III
Generic Oxycodone	Oxycodone hydrochloride	Schedule II
Generic Oxymorphone	Oxymorphone hydrochloride	Schedule II
Generic Hydromorphone	Hydromorphone hydrochloride	Schedule II
Generic Hydrocodone	Hydrocodone	Schedule II

36. In 2017, Endo Pharmaceuticals removed Opana ER from the market due to serious risks of abuse.[2]

37. Endo manufactures and sells its generic opioids both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc.

38. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation, with its principal place of business in Titusville, New Jersey. Jansen Pharmaceuticals is a wholly owned subsidiary of Defendant Johnson & Johnson. Janssen Pharmaceuticals was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceuticals, Inc.

39. Defendant Johnson & Johnson ("J&J") is a publicly traded New Jersey corporation, with its principal place of business in New Brunswick, New Jersey. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs, and Janssen Pharmaceuticals' profits inure to J&J's benefit.

40. At all times material hereto, Defendants Janssen Pharmaceuticals and J&J (collectively, "Janssen") manufactured, promoted, marketed, and sold opioids nationally and in

[2] *See* Opana Form 10-Q for the quarter ended June 30, 2017, 22, http://www.endo.com/investors/sec-filings.

Philadelphia, including but not limited to the following:

Table 5. Janssen Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta	Tapentadol	Schedule II
Nucynta ER	Tapentadol extended release	Schedule II
Ultram	Tramadol hydrochloride	Schedule IV

41. J&J is one of the world's largest legal poppy growers. J&J supplies precursor opium for much of the hydrocodone and oxycodone consumed in the United States.

42. Purdue, Allergan/Actavis, Cephalon, Endo, and Janssen are collectively referred to herein as the "Manufacturer Defendants."

B. The Distributor Defendants

43. Defendant AmerisourceBergen Drug Corp. ("AmerisourceBergen"), through its various subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Philadelphia. AmerisourceBergen is the twelfth largest company by revenue in the United States, with annual revenue of more than $153 billion in 2017. AmerisourceBergen is incorporated in Delaware and its principal place of business is located in Chesterbrook, Pennsylvania.

44. Defendant Cardinal Health, Inc. ("Cardinal") is the fifteenth largest company by revenue in the United States with $130 billion in revenue in 2017, a 7% increase over the previous year. Cardinal is incorporated and headquartered in Ohio. Cardinal distributes opioids and other pharmaceutical drugs throughout the United States, including in Philadelphia.

45. Defendant McKesson Corporation ("McKesson") is the largest pharmaceutical distributor in the United States and the sixth largest company by revenue, with $198.5 billion in revenue in 2017. McKesson is a wholesale distributor of pharmaceutical drugs, including

opioids. McKesson's principal place of business is in San Francisco, California and the company is incorporated in Delaware.

46. AmerisourceBergen, Cardinal, and McKesson are referred to collectively herein as the "Distributor Defendants."

GENERAL ALLEGATIONS

I. Prescription Opioids and Their Adverse Health Effects

47. Most prescription opioids are natural and semi-synthetic drugs derived from the active ingredients of opium. Prescription opioids include the drug formulations identified herein. The most commonly prescribed are formulations (both branded and generic) of hydrocodone, oxycodone, oxymorphone and hydromorphone.[3]

48. Opium and opium derivatives including prescription opioids have both pain relieving and euphoria-inducing characteristics. The pain-relieving properties of opium have been recognized for millennia. During and after the Civil War, opioids, sometimes known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain, and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

49. Unfortunately, prescription opioids pose the same dangers and hazardous side effects associated with opium and opium derivatives such as morphine and heroin, and have a high degree of potential for abuse and addiction. Opium (or the active ingredients thereof) is the foundational component of heroin and prescription opioids, and both types of drugs function in an essentially identical fashion.

50. Prescription opioids work by binding to receptors on the spinal cord and in the

[3] Fentanyl is also a prescription opioid and the subject of deceptive marketing and misuse. Fentanyl is a wholly synthetic prescription opioid that is similar to morphine, but is 50 to 100 times more potent. *See* https://www.drugabuse.gov/drugs-abuse/fentanyl.

brain, altering the perception of pain. Opioid addiction is a medical disease that arises from repeated exposure to opioids. It can occur in individuals using prescription opioids to relieve pain under the supervision of a physician at prescribed doses, just as it can occur in individuals using opioids for non-medical purposes.

51. Discontinuing opioid use even after just a few days of therapy can cause patients to experience withdrawal symptoms. The odds an individual will still be on opioids a year after starting a short course increase after only 5 days of being on opioids. Withdrawal symptoms can include anxiety, nausea, vomiting, agitation, insomnia, muscle aches, abdominal cramping, and other serious conditions, which may persist for months or longer after a complete withdrawal from opioids, depending on how long the opioids were used.[4]

52. When opioids are used over time, patients grow tolerant to their analgesic and euphoric effects. As tolerance increases, a patient requires progressively higher doses in order to obtain the same levels of pain reduction to which he or she has become accustomed.[5] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at an even higher risk of addiction.[6]

53. Opioids can cause severe respiratory depression (meaning that breathing slows to the point that the body cannot adequately exhale carbon dioxide), coma, and/or death. These serious hazards can occur even when used at prescribed doses, and can affect – sometimes fatally

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[4] *See, e.g.*, Health Guide: Opiate Withdrawal, The New York Times (2013), http://www.nytimes.com/health/guides/disease/opiate-withdrawal/overview.html?mcubz=3.

[5] M. Katz, Long-Term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

[6] In a study conducted by Kidner and colleagues, they found that higher doses of opioids (greater than 61 mg/day of morphine equivalents) predicted worse outcomes, including program non-completion, lower rates of return to work, and higher health care utilization. Furthermore, studies have shown that the prevalence of mental health diagnoses increases with increasing duration of opioid use. *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3641146/.

– even users who are not suffering from opioid addiction or opioid use disorder.

54. Up to the mid-1990s, the medical profession viewed opioids as having legitimate uses, but believed that they should be prescribed cautiously and only on a limited basis, because of concerns about addiction, tolerance leading to dose escalation, and physiological dependence resulting in difficulty discontinuing use. Physicians were reluctant to prescribe opioids on a long-term basis for common chronic pain conditions because of their addiction risks and side effects.[7]

55. In the late 1990s, however, the rate of prescription opioid use, particularly for the treatment of chronic pain, began accelerating rapidly. In the early 1990s, the number of opioid prescriptions at U.S. pharmacies increased by two to three million each year. From 1995 to 1996, the number of prescriptions jumped by eight million. This acceleration was directly related to, coincided with, and was caused by, efforts of the Manufacturer Defendants to falsely and deceptively promote the benefits of long-term prescription opioid use and minimize the risks of prescription opioids in order to take advantage of the lucrative market for chronic pain patients. The Manufacturer Defendants' efforts in this regard are alleged more fully below.

56. The crisis is also the result of the Distributor Defendants' failure to effectively control the distribution of prescription opioids, which they knew to be dangerous and highly addictive.

57. The Distributor Defendants failed to identify and report suspicious orders of opioids to the appropriate regulatory agencies, as required by law. Instead, the Distributor Defendants filled those orders, substantially contributing to the opioid crisis.

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[7] Andrew Kolodny *et al.*, The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, 562 (Jan. 12, 2015) (hereinafter "Kolodny, Jan. 12, 2015"), https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.

58. The Distributor Defendants sold and distributed opioids in far greater quantities than they knew to be necessary for legitimate medical uses, fueling a vast illegal secondary market that has contributed to the current opioid-related crisis in Philadelphia. Illegal opioid sales were channeled through "pill mills," which often presented as "pain clinics" with licensed medical professionals selling high volumes of prescription opioids illegally. The Distributor Defendants refused to comply with their licensing requirements and stop suspicious orders of opioid pills, which facilitated a limitless supply of opioid pills to the increasing number of people suffering from opioid addiction.

59. As a result of Defendants' deceptive conduct, the opioid crisis in Philadelphia worsened and became so severe that on October 3, 2018, Mayor Jim Kenney declared a disaster in Kensington, Philadelphia's most opioid-plagued neighborhood, and called for the establishment of an emergency operations center. The problems to be addressed through the new emergency operations center include reducing overdose deaths, reducing homelessness, increasing access to effective treatment for addiction, and reducing open-air drug use and sales.[8] The New York Times referred to Kensington as the "Walmart of Heroin" and reported that Kensington is the largest open-air heroin market on the East Coast.[9]

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[8] Aubrey Whelan, Declaring a Disaster In Opioid-Plagued Kensington, Philadelphia Officials Announce a New Rescue Plan, Philadelphia Inquirer, (Oct. 3, 2018), http://www2.philly.com/philly/health/addiction/declaring-opioid-plagued-kensington-a-disaster-philadelphia-officials-announce-a-new-rescue-plan-20181003.html.

[9] Jennifer Percy, Trapped by the 'Walmart of Heroin', New York Times (Oct. 10, 2018), https://www.nytimes.com/2018/10/10/magazine/kensington-heroin-opioid-philadelphia.html.

60. Scientific evidence has not demonstrated the safety or efficacy of prescription opioids for long-term daily use to treat chronic pain.[10]

61. As a result of widespread, scientifically unsupported use of prescription opioids for long-term chronic pain, the U.S. Centers for Disease Control and Prevention ("CDC") developed the "CDC Guideline for Prescribing Opioids for Chronic Pain" in March 2016 (the "2016 CDC Guideline").[11] The 2016 CDC Guideline extensively discussed the evidence (and lack thereof) supporting opioid use to treat chronic pain.

62. Chronic pain generally refers to pain lasting three months or longer. In the 2016 CDC Guideline, the CDC stated: "Chronic pain has been variably defined but is defined within this [opioid treatment] guideline as pain that typically lasts >3 months or past the time of normal tissue healing. Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause."[12]

63. As indicated by the CDC, there are no controlled studies of the use of opioids to treat chronic pain beyond 12 weeks, and no reliable evidence that opioids improve patients' pain and function long-term.[13]

64. Based on a detailed review of prior opioid studies, the CDC concluded that "evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains

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[10] The National Institutes of Health and the Agency for Healthcare Research and Quality issued a report that found no evidence for effectiveness of long-term opioid use for chronic pain, but a disquieting amount of evidence for harm, including overdoses and addiction. *See* https://www.painresearchforum.org/news/46387-long-term-opioid-therapy-chronic-pain-more-harm-good.

[11] CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, The Center for Disease Control and Prevention, (March 18, 2016) (hereinafter "*CDC Guideline*, March 18, 2016"), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

[12] *Id.* at pg. 1.

[13] *Id.* at pg. 2, 9.

limited, with insufficient evidence to determine long-term benefits versus no opioid therapy."[14] The CDC further stated: "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . . ."[15] The 2016 CDC Guideline also stated: "Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)."[16] A study by the New England Journal of Medicine concluded that the risks of extended prescriptions of opioids for the treatment of chronic pain, the risk of overdose and addiction increase with higher doses, longer duration of prescribing, and perhaps the use of long-acting opioids. Despite these facts, a Medicaid study showed that more than 50% of opioids prescriptions were for doses higher than 90 morphine milligram equivalents (MME) and for periods of more than 6 months.[17]

65. As referred to in the 2016 CDC Guideline, the first randomized, placebo controlled studies appeared in the 1990s, and revealed evidence only for *short-term* efficacy of opioids, and only in a minority of patients.[18] Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently noted the lack of available data to assess long-term outcomes.

66. On the other hand, substantial evidence exists indicating that opioid drugs are *ineffective* to treat chronic pain, and actually *worsen* patients' health. While opioids may work to control pain in short-term applications, long-term use very often leads to a decline in the patient's overall functionality, general health, mental health, and social function. A study conducted by the U.S. Department of Health and Human Services concluded that higher doses of

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[14] *Id.* at pg. 9 (emphasis added).
[15] *Id.* at pg. 15.
[16] *Id.* at pg. 15.
[17] Nora D. Volkow, M.D. and A. Thomas McLellan, Ph.D., Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies, N. Engl. J. Med. 2016, https://www.nejm.org/doi/full/10.1056/NEJMra1507771.
[18] Nathaniel Katz, Opioids: After Thousands of Years, Still Getting to Know You, 23(4) Clin. J. Pain 03 (2007); Roger Chou *et al.*, Research Gaps on Use of Opioids for Chronic Noncancer Pain, 10(2) J. Pain 147 (2009).

opioids are associated with a greater risk of physical dependence, fractures, heart problems and endocrine effects.[19]

67. Studies have shown that increasing the duration of opioid use is strongly associated with an increasing prevalence of negative mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater utilization of health care services. Over time, even high doses of opioids often fail to control pain due to tolerance levels rising, and many patients exposed to such doses are unable to function normally. Of people taking opioids for a year, as many as 8% ended up misusing or addicted to their medications while as many as 26% became physically dependent upon them.[20]

68. As a result of wide acknowledgment that opioids are neither safe nor effective for long-term use, in February 2017 the "Veterans Affairs/Department of Defense Clinical Practice Guideline for Opioid Therapy for Chronic Pain" strongly recommended "against initiation of long-term opioid therapy for chronic pain."[21]

II. The Manufacturer Defendants' False and Deceptive Conduct in Marketing Opioids

69. The Manufacturer Defendants improperly marketed opioids for years, using false and deceptive marketing that overstated and/or misrepresented the safety and efficacy of opioids and understated the risks of those drugs.

70. The Manufacturer Defendants' false and deceptive marketing was effective in

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[19] The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain, U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, No. 218, https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/chronic-pain-opioid-treatment_research.pdf.

[20] *See*, *supra* n. 10, https://www.painresearchforum.org/news/46387-long-term-opioid-therapy-chronic-pain-more-harm-good.

[21] Clinical Practice Guideline for Opioid Therapy for Chronic Pain, Department of Defense, Department of Veteran's Affairs, V:3, 7 (2017), https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf.

convincing prescribers, pharmacists, patients, third-party payors, pharmacy benefit managers, health plan administrators, and others responsible for selecting and approving prescription drugs (including opioids) covered by health insurance plans, that prescription opioids could be safely used on a long-term basis to treat chronic pain, that prescription opioids were an effective treatment for chronic pain, and that the benefits of using opioids to treat chronic pain far outweighed the risks.

71. The Manufacturer Defendants' marketing specifically targeted prescribers, pharmacists, and patients, as well as the individuals and groups responsible for selecting opioid drugs covered by health coverage plans and included on pharmacy formularies (*i.e.*, insurers, pharmacy benefit managers, and others).

72. The Manufacturer Defendants, however, knew that these marketing and product promotion claims were false, misleading, deceptive and likely to misinform or confuse the targets of the marketing and product promotion described above. Among other things, and as more fully set forth *supra*, the Manufacturer Defendants knew that controlled studies of the safety and efficacy of prescription opioids were limited to short-term use in monitored settings (*e.g.*, hospitals) where the risks of addiction, abuse, overdose, and other adverse outcomes were minimized, and that long-term studies demonstrating the safety and efficacy of prescription opioids for long-term use did not exist.

73. The Manufacturer Defendants also knew or disregarded the fact that the effectiveness of prescription opioids wanes with prolonged use, requiring increases in dosage to achieve ongoing pain relief, which markedly increases the risk of significant side effects, addiction, and overdose when used for long-term treatment.

74. Despite these facts – well known to Defendants for many years – the

Manufacturer Defendants sought to create a false perception of the safety and efficacy of prescription opioids for long-term daily use to treat chronic pain, including to treat a wide range of conditions including such common ones as lower back pain, arthritis, and headaches.

75. The Manufacturer Defendants engaged in this false and deceptive conduct because they recognized that chronic pain patients could provide a much larger, and far more lucrative, market for prescription opioids than patients with acute pain or cancer pain at the end of life. It is estimated that chronic pain affects one in five Americans and will afflict even more as the incidence of diseases such as diabetes, obesity, and arthritis rises in the aging population.[22] To take advantage of this potentially massive market, the Manufacturer Defendants engaged in these false and deceptive marketing activities to promote prescription opioids for the management of chronic pain, thereby consciously and unconscionably elevating corporate profits above the interest and well-being of patients.

76. The Manufacturer Defendants created a falsely favorable perception of prescription opioids through coordinated, sophisticated, and highly deceptive marketing that began in the mid-1990s and continues to the present.

77. In 1996, opioid sales and use began accelerating rapidly. This acceleration was triggered initially by the introduction in 1995 of Defendant Purdue's OxyContin, an extended release formulation of oxycodone, and by Purdue's aggressive marketing of OxyContin. Other Manufacturer Defendants followed suit and began to market aggressively their own prescription opioids in a similar manner. The rapid acceleration of sales and use of prescription opioids continued for two decades, as alleged and illustrated more fully in the graphs, *infra.*

78. During this time, the Manufacturer Defendants individually and collectively

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[22] James Dahlamer, *et al.*, Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults- United States, 2016, The Center for Disease Control (Sept. 14, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm?s_cid=mm6736a2_w.

poured vast financial resources into marketing their own opioid products, in a distortion of medical and public perceptions of prescription opioids, creating the false impression of a new "consensus" supporting the long-term daily use of opioids. The Manufacturer Defendants' false and deceptive tactics were wide-reaching and varied.

79. The Manufacturer Defendants made these false and deceptive statements concerning both their own branded opioids and prescription opioids generally. The Manufacturer Defendants made these misrepresentations directly in their oral and written marketing to prescribers, as well as indirectly through the use of third-party vehicles, including: (i) so-called "key opinion leaders" ("KOLs"), *i.e.*, physicians who influence their peers' medical practices and prescribing behavior, who wrote favorable journal articles and delivered supportive educational courses; (ii) "unbranded" educational materials for patients, physicians and others disseminated through groups purporting to be independent patient-advocacy and professional organizations ("Front Groups"), which exercised influence through Defendant-controlled KOLs who served in leadership roles in these organizations and which were directly or indirectly controlled by the Manufacturer Defendants; (iii) a body of biased and unsupported scientific literature which the Manufacturer Defendants directly or indirectly created, funded, or exploited; (iv) so-called "treatment guidelines" which the Manufacturer Defendants formulated or caused to be formulated and distributed or caused to be distributed; and (v) CMEs prepared and/or funded in whole or in part by the Manufacturer Defendants. These third parties and third-party vehicles are collectively referred to herein as the Manufacturer Defendants' "Third-Party Allies."

80. The Manufacturer Defendants' direct and indirect marketing through their Third-Party Allies was very effective. The Manufacturer Defendants' efforts successfully altered the prescribing practices of the medical community, thereby dramatically increasing opioid

prescriptions and use. These efforts also successfully influenced third-party payors, pharmacy benefit managers ("PBMs") and others responsible for maintaining and administering drug formularies on behalf of private and public health insurance plans.

81. A 2016 joint investigation conducted by the Associated Press and the Center for Public Integrity found that opioid manufacturers and allied groups spent more than $880 million over the past decade to influence state governmental policies in order to promote opioids.[23] Those manufacturers, including the Manufacturer Defendants, used the same deceptive practices and communications to influence policymakers, as well as the public.

82. In Pennsylvania, Defendant Purdue sat on a 38-member opioid task force and advisory committee chaired by a state legislator. After the group met in private with no publicly available transcripts or minutes of its meetings, it recommended that legislators enact a bill to promote abuse-deterrent opioids. The House held no public hearing on the bill, and the bill passed the Pennsylvania House 190-3.[24] However, Defendants' representations that abuse-deterrent formulations could help thwart addiction were deceptive and without scientific support.

83. Over-prescription of opioids resulting from the deceptive over-promotion by the Manufacturer Defendants led to an artificial inflation of demand for prescription opioids, including the creation of a population of users physically dependent on opioids, thereby leading to dramatically increased sales of prescription opioids, all to the improper and direct financial benefit of the Manufacturer Defendants.

84. The Manufacturer Defendants' broad false and deceptive marketing efforts have, indeed, been enormously profitable. In 2015 alone, prescription opioids generated $9.6 billion in

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[23] Marc Levy, Pennsylvania Opioid Debate May Include Push for Pricier Pill, The Morning Call (Sept. 18, 2016), http://www.mcall.com/news/nationworld/pennsylvania/mc-pa-politics-of-pain-pennsylvania-20160917-story.html.

[24] *Id.*

revenue for opioid manufacturers.[25] From 1996 to 2000, OxyContin sales increased from $48 million to almost $1.1 billion and did not decrease.[26] Defendant Purdue generated $35 billion alone in revenue from the sale of OxyContin from the product's inception to 2016.[27]

85. The vast demand for opioids today is sustained largely by the Manufacturer Defendants' prior success in false and deceptive marketing in establishing prescription opioids as a treatment for chronic pain. The current demand for prescription opioids is driven, to a significant extent, by individuals suffering from physiological dependence who require continued opioid prescriptions (and their agent-doctors who refill opioid prescriptions in the continued belief that opioids are safe in light of the Manufacturer Defendants' prior product promotion, as well as the Distributor Defendants' misleading statements and conduct described in more detail below) and new patients who, along with their physicians, wrongly believe that opioids are a viable and safe chronic pain treatment, among others.

86. The Manufacturer Defendants directed their false and deceptive marketing efforts not only to physicians, pharmacists and patients, but also to third-party payors, PBMs and other health plan administrators, including those responsible for approving the Manufacturer Defendants' drugs for inclusion on drug formularies.

87. Physicians, along with formulary committees of third-party payors and PBMs, rely upon a variety of sources including independent studies for information relating to the safety and efficacy of prescription drugs, which they prescribe or approve for use. However, often

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[25] D. Crow, Drugmakers Hooked on $10bn Opioid Habit, Financial Times (Aug. 10, 2016), https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[26] Art Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99(2): 221-227, Am. J. Public Health, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

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

unbeknownst to the public and other persons and entities, many of these sources are directly controlled or heavily influenced by pharmaceutical manufacturers such as the Manufacturer Defendants. Also, many of these sources of information are susceptible to exploitation by pharmaceutical manufacturers such as the Manufacturer Defendants.

88. The Manufacturer Defendants' violations of the law are not excused by the involvement of doctors in the prescription process or clinical evaluators at the third-party payors, PBMs or other health plan administrators, because they themselves were subject to and influenced by the Manufacturer Defendants' false and deceptive marketing. The Manufacturer Defendants' widespread and highly persuasive messages tainted many sources on which doctors and health plan administrators relied for information, and prevented them from making fully informed treatment decisions. The Manufacturer Defendants improperly targeted not only pain specialists, but also primary care physicians, nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the Manufacturer Defendants' misleading statements, as well as clinical evaluators at or used by health plan administrators.

A. The Manufacturer Defendants Used "Branded" and "Unbranded" Opioid Marketing to Deceive Physicians, Patients and PBMs

89. Drug companies' promotional activities can be characterized as "branded" or "unbranded." Branded marketing refers to marketing of a specific drug manufactured by a specific company. Unbranded marketing does not refer to the marketing of a specific drug or brand, but rather to a class of drugs, or to a particular disease, condition, or treatment.

90. The Manufacturer Defendants made false and deceptive statements in their branded marketing as alleged below. In addition to direct statements concerning safety and efficacy and in connection with their branded marketing, the Manufacturer Defendants also brought to the attention of their target audience – physicians, patients, third-party payors, PBMs

and others – the unbranded marketing alleged below.

1. *The Manufacturer Defendants' Deceptive Branded Marketing of Opioids*

91. The Manufacturer Defendants' branded marketing generally must not include false or misleading statements or material omissions about the safety and/or efficacy of the drug.

92. Drug companies, which are regarded as most knowledgeable about the properties and effects of their drugs, are responsible for providing prescribers, third-party payors, PBMs and other health plan administrators with information they need to accurately assess the risks and benefits of drugs for their patients and insureds.

93. The Manufacturer Defendants' product marketing and promotional statements that fail to state accurately the safety, efficacy and risks of a prescription drug or that fail to present the most important risks of the drug as prominently as its benefits are deceptive on their face or because they lack fair balance.

94. It is also deceptive for the Manufacturer Defendants to distribute materials or make promotional statements that exclude contrary evidence or information about the drug's safety or efficacy, or present conclusions that cannot be supported by the results of clinical or other studies.

95. Further, it is deceptive for the Manufacturer Defendants to make comparisons between their drugs and other drugs that represent or suggest that their drugs are safer or more effective than other drugs that treat the same condition, when they have not been demonstrated to be safer or more effective based on substantial evidence or substantial clinical experience.

96. To spread their false and deceptive messages supporting chronic opioid therapy, the Manufacturer Defendants marketed their branded opioids directly to health care providers nationwide and in the Philadelphia area. They did so principally through their sales force – sales representatives, also known as "detailers" -- who made in-person sales calls to prescribers in

which they misleadingly portrayed their branded opioids as safe, effective, and appropriate for the treatment of chronic pain.

97. For years, the Manufacturer Defendants relied heavily on their sales representatives to market opioids directly to prescribers and others, and that practice continues today, including in the Philadelphia area. For example, in 2014, the Manufacturer Defendants collectively spent $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. As another example, in 2016, Purdue spent $156 million on detailing out of $167 million in total advertising expenditures promoting opioids nationwide. Expenditures of these magnitudes are more than double the Manufacturer Defendants' collective spending on detailing in 2000. By establishing personal relationships with doctors and other prescribers, the Manufacturer Defendants' sales representatives are able to disseminate their misrepresentations in targeted, one-on-one settings.

98. The Manufacturer Defendants employed the same marketing tactics and messages in the Philadelphia area as they did regionally and nationwide, using uniform marketing materials and national and regional sales training. The Manufacturer Defendants carefully trained their sales representatives to deliver company-approved sales messages. The Manufacturer Defendants exactingly directed and monitored their sales representatives – through detailed action plans, trainings, tests, scripts, role-plays, and supervisor tag-alongs – to ensure that individual sales representatives actually delivered the Manufacturer Defendants' desired messages.

99. The Manufacturer Defendants encouraged or required their sales representatives to make in-person detailing visits to multiple prescribers per day. Many of these prescribers

were visited repeatedly, often monthly or more frequently. In addition, detailers often had to meet individual sales quotas .

100. The Manufacturer Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. The Manufacturer Defendants purchased and closely analyzed prescription sales data from IMS Health (the largest vendor of physician prescribing data to the medical community). This data allowed them to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allowed them to target, tailor, and monitor the impact of their detailing efforts.

101. The Manufacturer Defendants relied upon "influence mapping," i.e., using rankings or similar breakdowns to identify high-volume prescribers on whom detailing would have the greatest sales impact. Endo, for example, identified prescribers representing 30% of its nationwide opioid sales volume and planned to visit those physicians three times per month. The Manufacturer Defendants also closely monitored doctors' prescribing activity after a sales representative's visit to allow the Manufacturer Defendants to refine their planning and messaging and to evaluate and compensate their detailers.

102. During the relevant time period, Manufacturer Defendants' sales representatives made thousands of detailing visits to physicians in Philadelphia. They spread misinformation regarding the risks, benefits, and superiority of Defendants' opioids for treatment of chronic pain.

103. The Manufacturer Defendants collectively spent hundreds of millions of dollars promoting opioid drugs via their respective sales forces, including in the Philadelphia area, because they knew their sales strategies were highly effective. Numerous studies indicate that marketing by drug manufacturers influences doctors' prescribing habits. Face-to-face detailing

typically has the highest influence of any marketing practice on a physician's intent to prescribe. The Manufacturer Defendants saw this phenomenon at work not only in the aggregate, as their sales climbed with promotional spending, but also at the level of individual prescribers they targeted for detailing who responded by prescribing more opioid drugs to more patients.

104. In addition to making deceptive claims in-person through detailers, the Manufacturer Defendants engaged in printed advertising campaigns touting the benefits of their branded opioids, including in the Philadelphia area. The Manufacturer Defendants published print advertisements in a broad array of medical journals ranging from those aimed at specialists, such as the *Journal of Pain and Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. Several of the Manufacturer Defendants' advertising budgets peaked in 2011, when they collectively spent more than $14 million on medical journal advertising of opioids, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo. Actavis' and Cephalon's medical journal advertising peaked earlier, with Actavis spending $11.7 million in 2005, and Cephalon spending about $2 million in each of 2007 and 2008.

105. The Manufacturer Defendants were deliberately deceptive in their portrayal of the risks and benefits of chronic opioid therapy in these branded advertisements. For example, in 1998 and 2000, Purdue distributed to doctors thousands of copies of videos, titled "I Got My Life Back," which made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients. And a 2005 ad that ran in pain medicine journals misleadingly implied that OxyContin could lead to long-term improvement in patients' pain, function, and quality of life, touting OxyContin as an "around-the-clock analgesic . . . for an extended period of time" and featuring a

man and a boy fishing under the tagline "There Can Be Life With Relief." The ads falsely implied that OxyContin provides effective long-term pain relief as well as functional improvement, claims that are unsubstantiated and contradicted in medical literature. Upon information and belief, these ads were circulated in the Philadelphia area.

106. The Manufacturer Defendants also engaged in branded marketing to physicians through voice mail, postcards, and email – so-called "e-detailing."

2. *The Manufacturer Defendants' Deceptive Unbranded Marketing of Opioids*

107. In addition to direct branded product promotion, the Manufacturer Defendants disseminated false, misleading, and unsubstantiated statements on a massive scale through unbranded marketing materials – that is, materials that promoted prescription opioid use but did not identify a specific opioid drug. Through these unbranded materials and statements, the Manufacturer Defendants presented information and guidelines concerning prescription opioids generally that were false and misleading.

108. Furthermore, by acting through third parties, the Manufacturer Defendants were able to give the false appearance that their messages reflected the views of independent, unbiased sources.

109. The Manufacturer Defendants falsely cited to these sources as "independent" corroboration of their own statements.

110. The Manufacturer Defendants' engineered third-party documents and marketing not only had greater credibility, but also broader diffusion among practitioners in the medical profession. Generally, doctors did not resist receiving materials from purportedly independent entities on display in their offices, as they might with drug company pieces.

111. The Manufacturer Defendants disseminated many of their false, misleading, and

unsubstantiated promotional messages through their Third-Party Allies because the messages appeared to uninformed or misled observers to be independent. Through unbranded materials, the Manufacturer Defendants presented information and guidance concerning opioids that were false, misleading, unsubstantiated, and/or incomplete, including in the Philadelphia area.

112. Even where the Manufacturer Defendants disseminated unbranded messages through their Third-Party Allies, the Manufacturer Defendants adopted those messages as their own when they cited to, edited, approved, and distributed such materials in their direct marketing activities knowing they were false, misleading, unsubstantiated, and/or incomplete.

113. As described herein, the Manufacturer Defendants' sales representatives regularly distributed false and deceptive third-party marketing materials to the Manufacturer Defendants' target audiences, including physicians, patients, and others such as pharmacy benefit managers, formularies, insurers, third-party payors, health plan administrators and other participants in the prescribing third-party approval chain, including in the Philadelphia area.

114. The Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by third parties, ensuring that the Manufacturer Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, the Manufacturer Defendants exercised control over their deceptive messages and acted in concert with these third parties to promote the use of prescription opioids for the treatment of chronic pain.

115. The unbranded marketing materials that the Manufacturer Defendants assisted in creating and disseminating failed to disclose properly the risks of opioid addiction, abuse, misuse, and overdose, or wrongfully denied or minimized those risks as alleged more fully herein. Those materials also misrepresented or concealed information concerning the efficacy of

prescription opioids as a treatment for chronic pain.

B. The Manufacturer Defendants' Use of Key Opinion Leaders to Further Their Deceptive Marketing

116. The Manufacturer Defendants cultivated a select group of doctors who were chosen and sponsored by the Manufacturer Defendants solely because they favored the aggressive treatment of chronic pain with prescription opioids. Pro-opioid doctors were the hub of the Manufacturer Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. Doctors hired by pharmaceutical companies to influence prescribing practices of their peers are known as key opinion leaders or KOLs.

117. These pro-opioid doctors wrote, consulted on, edited, and lent their names to numerous books and articles, and gave speeches and Continuing Medical Education courses ("CMEs") supportive of opioid therapy for treatment of chronic pain.

118. The KOLs served on committees that developed so-called "treatment guidelines" that strongly encouraged the use of prescription opioids to treat chronic pain, and on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs, including in the Philadelphia area. The Manufacturer Defendants were able to exert control of each of these modalities through their KOLs.

119. In return for their pro-opioid advocacy, the Manufacturer Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. It is now clear that written and oral statements by the Manufacturer Defendants' KOLs were false and/or misleading or lacked reasonable medical or scientific basis in fact.

120. The Manufacturer Defendants cited and promoted their KOLs – and studies or articles by their KOLs – to broaden the chronic opioid therapy market. By contrast, the

Manufacturer Defendants did not support, acknowledge, or disseminate the publications or studies of doctors who were critical of the use of chronic opioid therapy.

121. The Manufacturer Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Manufacturer Defendants' agenda. The Manufacturer Defendants also kept close tabs on the content of the materials published by these KOLs.

122. In their promotion of the use of opioids to treat chronic pain, the Manufacturer Defendants' KOLs knew or recklessly disregarded the possibility that their statements were false and misleading, but they continued to deliver their misleading messages to benefit themselves and the Manufacturer Defendants. Two of the Manufacturer Defendants' most prominent KOLs are described below.

1. *Dr. Russell Portenoy's Role in the Manufacturer Defendants' Deceptive Marketing of Opioids*

123. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaigns.

124. Dr. Portenoy received research support, consulting fees, and honoraria from Defendants Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

125. Dr. Portenoy was instrumental in opening the door for the regular use of prescription opioids to treat chronic pain. He served on the American Pain Society ("APS") and American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of prescription opioids to treat chronic pain first in 1997 and again in 2009. He was also a member of the board of American Pain Foundation ("APF"), an advocacy organization almost

entirely funded by the Manufacturer Defendants.

126. Dr. Portenoy also made frequent media appearances promoting prescription opioids and spreading misrepresentations on the Manufacturer Defendants' behalf.

127. For example, he appeared on *Good Morning America* in 2010 to discuss the use of opioids to treat chronic pain. On this widely watched program, 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."[28]

128. Dr. Portenoy subsequently admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[29] Among other things, these lectures falsely claimed 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 that promoted them overstated opioids' benefits and glossed over their risks.

129. Dr. Portenoy also conceded to *The Wall Street Journal* that "[d]ata about the effectiveness of opioids does not exist."[30] He candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[31]

130. Bloomberg reported that Dr. Portenoy "recanted publicly in 2011, conceding that research he relied on to push his and Purdue's pro-opioid campaign didn't prove anything about

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[28] *Good Morning America* television broadcast, ABC News (Aug. 30, 2010).

[29] Thomas Catan *et al.*, A Pain-Drug Champion Has Second Thoughts, The Wall Street Journal (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[30] *Id.*

[31] *Id.*

the treatment of chronic pain."[32]

2. *Dr. Lynn Webster's Role in the Manufacturer Defendants' Deceptive Marketing of Opioids*

131. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, a small pain clinic in Salt Lake City, Utah. In 2013, Dr. Webster was the President and a former board member of AAPM, a front group that ardently supports chronic opioid therapy. He was a Senior Editor of *Pain Medicine*, the same journal that published Defendant Endo's special advertising supplements touting Opana ER.

132. Dr. Webster taught numerous CMEs sponsored by Defendants Cephalon, Endo, and Purdue. At the same time, Dr. Webster received significant funding from the Manufacturer Defendants, including nearly $2 million from Defendant Cephalon.

133. Dr. Webster was investigated by the DEA for overprescribing opioids. The DEA raided his clinic in 2010.[33] More than 20 of Dr. Webster's former patients at the Lifetree Clinic died of opioid overdoses.

134. Dr. Webster created and promoted the Opioid Risk Tool,[34] a ten question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appeared on, or were linked

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[32] Esme Deprez, The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry, Bloomberg Businessweek (Oct. 5, 2017), https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.

[33] Stephanie Smith, Prominent Pain Doctor Investigated by DEA After Patient Deaths, CNN (Dec. 20, 2013), http://www.cnn.com/2013/12/20/health/pain-pillar/index.html.

[34] Lynn R. Webster, The Opioid Risk Tool, https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf

to, websites run by Defendants Endo, Janssen, and Purdue.

135. In 2011, Dr. Webster presented, via webinar, a program sponsored by Defendant Purdue titled *Managing Patient's Opioid Use: Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was – and still is – available to doctors nationwide.[35]

136. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the 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 addiction and undertreated pain was to increase a patient's dose of opioids. As he and his co-author wrote in a book titled *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."[36] Defendant Endo distributed this book to many doctors.

137. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[37]

138. Doctors Portenoy and Webster are only examples of KOLs and their cooperation

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[35] Managing Patient's Opioid Use: Balancing the Need and the Risk, Emerging Solutions to Pain (Nov. 1, 2011), http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209.

[36] *See* Lynn R. Webster, Avoiding Opioid Abuse While Managing Pain (2007), excerpt available at https://books.google.com/books?id=1C_DRcKq_KwC&pg=PT99&lpg=PT99&dq=%22Avoiding+Opioid+Abuse+While+Managing+Pain%22+%22clinician%E2%80%99s+first+response%22&source=bl&ots=DctEK1gFua&sig=IQiikIPhKQldfmLayEF-YlDTRfo&hl=en&sa=X&ved=0ahUKEwiZ7aep78DWAhVl0FQKHUF3CjUQ6AEIJjAA#v=onepage&q=%22Avoiding%20Opioid%20Abuse%20While%20Managing%20Pain%22%20%22clinician%E2%80%99s%20first%20response%22&f=false.

[37] John Fauber *et al.*, Networking Fuels Painkiller Boom, Milwaukee Wisconsin Journal Sentinel (Feb. 19, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/.

with the Manufacturer Defendants. On information and belief, a number of other similarly compromised KOLs also cooperated with the Manufacturer Defendants.

139. Misleading statements and materials created by KOLs were directly or indirectly disseminated to patients, physicians, and others including third-party payors, PBMs and other health plan administrators.

140. Between August of 2013 and December of 2015, more than 375,000 opioid-related payments were made to more than 68,000 physicians in the U.S. One in twelve physicians, and one in five family doctors, accepted a payment related to a prescription of opioid from 2013 to 2015.[38]

C. The Manufacturer Defendants' Misuse of Patient and Physician Education Materials and Front Groups to Further Their Deceptive Marketing of Opioids

141. Pharmaceutical industry marketing experts view patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[39]

142. Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true for opioids and conditions for which they are not approved.[40]

143. Recognizing this phenomenon, the Manufacturer Defendants worked with Front Groups to engage in largely unbranded marketing directly to patients about opioid treatment for

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[38] David Orenstein, Opioids Makers Made Payments to One in Twelve U.S. Doctors, New from Brown University (Aug. 9, 2017), https://news.brown.edu/articles/2017/08/opioids-influence.

[39] Kanika Johar, An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices, 76 Albany L. Rev. 299, 308 (2013).

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

chronic pain.

144. The Manufacturer Defendants entered into arrangements with numerous Front Groups to promote opioids. These organizations depended upon the Manufacturer Defendants for significant funding and, in some cases, for their survival.

145. The Front Groups generated materials and programs for doctors and patients that supported chronic opioid therapy, responded to unfavorable articles about the dangers of prescription opioids, and lobbied against regulatory changes that would constrain opioid prescribing.

146. The Front Groups developed and disseminated pro-opioid treatment guidelines; conducted outreach to patient groups targeted by the Manufacturer Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of prescription opioids to treat chronic pain.

147. The Manufacturer Defendants funded the Front Groups to ensure the delivery of favorable messages from seemingly neutral and credible third parties.

148. The following are examples of the Front Groups used by the Manufacturer Defendants to further their deceptive marketing:

1. *The American Pain Foundation's Role in Defendants' Deceptive Marketing of Opioids*

149. APF, the most prominent of the Front Groups, received more than $10 million in funding from opioid manufacturers from 2007 until it ceased operations in May 2012.

150. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of prescription opioids for chronic pain and trivialized the risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign through radio, television and the internet to purportedly "educate" patients about their "right" to

pain treatment with opioids.

151. All of APF's programs and materials were intended to, and did, reach a national audience, including within Philadelphia.

152. By 2011, APF was dependent on grants from Defendants Purdue, Cephalon and Endo for funding, which also enabled APF to avoid using its line of credit. APF board member, KOL Dr. Portenoy, explained that the lack of funding diversity was one of the biggest problems at APF.

153. APF held itself out as an independent patient advocacy organization, yet engaged in grassroots lobbying efforts against various legislative initiatives that would limit opioid prescribing. In reality, APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients.

154. In practice, APF operated in close collaboration with the Manufacturer Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by the Manufacturer Defendants. APF also assisted in marketing projects for the Manufacturer Defendants.

155. The close relationship between APF and the Manufacturer Defendants demonstrates APF's clear lack of independence in its finances, management, and mission. APF's willingness to allow the Manufacturer Defendants to control its activities and messages indicates that each Defendant that worked with it was able to exercise editorial control over its publications.

156. In May 2012, the U.S. Senate Finance Committee began investigating APF to determine the links, financial and otherwise, between the organization and manufacturers of opioid painkillers.

157. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately."[41]

2. *The American Academy of Pain Medicine's Role in the Manufacturer Defendants' Deceptive Marketing of Opioids*

158. The AAPM, with the assistance, prompting, involvement and funding of the Manufacturer Defendants, issued the treatment guidelines discussed above, and sponsored and hosted CMEs essential to Defendants' marketing plans.

159. AAPM received over $2.2 million in funding since 2009 from the Manufacturer Defendants and other drug manufacturers.

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

161. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented marketing programs to doctors who attended this annual event.

162. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – for example 37 out of roughly 40 sessions at one conference alone addressed opioids.

163. AAPM's list of past presidents includes top industry-supported KOLs Dr.

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[41] Charles Ornstein and Tracy Weber, American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics, ProPublic (May 8, 2012), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

Portenoy, Dr. Perry Fine, and Dr. Lynn Webster. Dr. Webster was elected president of AAPM while the DEA was investigating his practice.

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

D. The Manufacturer Defendants' Corruption of Scientific Literature to Further Their Deceptive Marketing of Opioids

165. Rather than actually study the safety and efficacy of opioids for long-term use, the Manufacturer Defendants deceived physicians, patients, and health plan administrators into believing that such studies had already been conducted.

166. The Manufacturer Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the effectiveness of long-term opioid use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions and purchasing decisions of prescribers, patients, and health care payors. This literature was, in fact, marketing material intended to persuade doctors, patients, and third-party payors that the benefits of long-term prescription opioid use outweighed the risks.

167. To accomplish their goal, the Manufacturer Defendants – sometimes through their Third-Party Allies or other third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of misleadingly favorable articles in academic journals.

168. The articles did not originate in professional organizations that engaged in research, development, or any other area that would confer specialized knowledge about opioid drugs. Rather, these purportedly academic articles originated in the Manufacturer Defendants' marketing departments and with the Manufacturer Defendants' marketing and public relations

consultants.

169. One commentator noted, regarding the pharmaceutical industry generally: "To give you an idea of how much the drug industry values sales and advertising, the fact is that Big Pharma spends more on that than on actual drug research and development."[42]

170. In these marketing materials, the Manufacturer Defendants or their surrogates often claimed to rely on "data on file" or presentation posters, neither of which was subject to peer review or other scientific safeguards or reliability. Still, the Manufacturer Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that the Manufacturer Defendants' materials were not based on reliable data or the use of normal practices of scientific safeguards to assure reliability and were not subject to the scrutiny of others who are experts in the same field.

171. The Manufacturer Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Manufacturer Defendants knew that the articles distorted the significance or meaning of the underlying study.

172. Notably, Purdue frequently cited a 1980 item in the well-respected New England Journal of Medicine – J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter") – in a manner that makes it appear that the item reported the results of a peer reviewed study. The Manufacturer Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter to the editor, not a study, much less a peer-reviewed study. The letter merely states that the authors examined their files of hospitalized patients who were prescribed opioids, and summarized what they found. The Porter & Jick Letter is reproduced here, in its entirety:

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[42] Jake Novak, Big Pharma's Opioid Mess is About to Hit the Industry – Hard, CNBC (Oct. 18, 2017), https://www.cnbc.com/2017/10/18/how-opioid-crisis-will-crush-big-pharma-commentary.html.

173. The patients referred to in the Porter & Jick Letter were all treated prior to 1980 when the letter was published. Because of standards of care prior to 1980, the use of opioid treatment was limited to acute or end-of-life situations, as opposed to long-term use for chronic pain.

174. The letter notes that the authors found almost no references in patient records to signs of addiction. However, there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor is there any indication whether the patients were monitored after they were discharged from the hospital.

175. None of these serious limitations was disclosed when the Manufacturer Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are safe and rarely addictive. Dr. Jick later complained that his letter had been distorted and misused.

176. The Manufacturer Defendants' campaign of misinformation continues. For example, a Purdue-funded study in 2017 in the *Journal of Managed Care & Specialty Pharmacy* stated: "[N]early 100 million Americans live with chronic pain . . . . For moderate to severe pain, opioids can provide significant symptom relief."[43] The study made no reference to the risks of using opioids or the distinction in both efficacy and risk between short-term and long-term use.

177. The Manufacturer Defendants wrongfully created and promoted favorable studies in medical literature, and discredited or suppressed negative information about prescription opioids. The Manufacturer Defendants' studies and articles often had the goal of debunking articles that contradicted the Manufacturer Defendants' claims or raised concerns about chronic opioid therapy.

178. The Manufacturer Defendants' strategy – to plant and promote pro-opioid literature and then cite that evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – resulted in egregiously deceptive and misleading marketing and promotion. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding risks and benefits of prescription opioids for long-term pain relief.

179. The Manufacturer Defendants' false and deceptive statements and scientific literature were directly or indirectly disseminated to patients, physicians, and others including third-party payors, PBMs and other health plan administrators.

180. The Manufacturer Defendants' promotion of opioids via false, deceptive, misleading and incomplete statements in the medical and scientific literature did not stop at the

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[43] Noam Kirson *et al.*, The Economic Burden of Opioid Abuse: Updated Findings, Journal of Managed Care & Specialty Pharmacy, 427 (April 2017), http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.

physician level, but also was aimed at, and directly and indirectly received by, other participants in the opioid marketing process including third-party payers and PBMs. For example, as part of the formulary listing process described below, manufacturer representatives submitted written materials, such as formulary dossiers and other written descriptions of the drugs, which in turn incorporated misleading data concerning the particular drug.

181. The Manufacturer Defendants' representatives also disseminated other false, deceptive and misleading medical literature about opioids to third-party payors, PBMs and others, including so-called "studies" and other statements as alleged more fully herein that, in turn, relied on highly misleading statements concerning the alleged benefits and safety of opioids such as the Portenoy and Porter & Jick materials noted above.

E. The Manufacturer Defendants' Misuse of Treatment Guidelines and Consensus Statements to Further Their Deceptive Marketing of Opioids

182. "Treatment guidelines" and consensus statements have been particularly important in securing acceptance for long-term opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors targeted by the Manufacturer Defendants, who generally are not experts and have no special training in the treatment of chronic pain.

183. Treatment guidelines and consensus statements not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and are relied on by third-party payors and PBMs in determining whether prescription opioids can be listed as approved pain relievers and whether they should pay for treatments for specific indications.

1. *The Federation of State Medical Boards Was a Target of the Manufacturer Defendants' Deceptive Marketing of Opioids*

184. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States, including medical boards in

Pennsylvania and the Philadelphia area. State boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

185. Defendants Purdue, Endo, and Cephalon have provided grants to the FSMB to finance opioid-specific and pain-specific programs.[44]

186. Since 1998, the FSMB has been developing state medical board policies for the use of opioids to treat pain. The 1998 version, titled *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("1998 Guidelines"), was produced "in collaboration with pharmaceutical companies." With the influence of the Manufacturer Defendants' marketing, the 1998 Guidelines provided not that opioids could be appropriate in limited cases after other pain treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

187. A 2004 version of the 1998 Guidelines, and a 2007 book titled *Responsible Opioid Prescribing: A Physician's Guide* ("Responsible Opioid Prescribing"), also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach and did reach physicians nationwide, including in the Philadelphia area.

188. The publication and distribution of *Responsible Opioid Prescribing* was backed largely by drug manufacturers including some or all the Manufacturer Defendants. In all, 163,131 copies were distributed by state medical boards (and through the boards, to practicing doctors). Some 601 copies were distributed in Pennsylvania, including some in the Philadelphia area.[45]

189. Having influenced the 1998 Guidelines, the Manufacturer Defendants also used

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[44] Ltr. from FSMB to U.S. Senate regarding Senate review of opioid abuse issues, 11-14, (June 8, 2012), https://assets.documentcloud.org/documents/3109089/FSMB-Response-Letter-to-US-Senate.pdf.

[45] *Id.* at pg. 19.

them to help convey the alarming message that "under-treatment of pain" could result in official discipline, and that no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.

190. The Manufacturer Defendants' (and their Third-Party Allies') worked with the FSMB to turn doctors' fear of discipline on its head: doctors, who formerly believed that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be reprimanded if they failed to prescribe opioids to their patients with chronic pain.

2. *American Academy of Pain Medicine/American Pain Society Guidelines' Role in Defendants' Deceptive Marketing of Opioids*

191. The AAPM and APS are professional medical societies, each of which received substantial funding from the Manufacturer Defendants.

192. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[46] The chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was KOL Dr. Portenoy. The consensus statement, which also formed the foundation of the Defendant-influenced 1998 Guidelines, was published on the AAPM's website and distributed to new AAPM members until 2012.

193. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Defendants Janssen, Cephalon, Endo and Purdue.

194. The 2009 Guidelines promoted opioids as "safe and effective" for treating chronic

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

pain, and concluded that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel for Defendants and have influenced not only treating physicians, but also the body of scientific evidence addressing opioids. They were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were and are available online, and were made available nationwide and in Philadelphia.

195. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines as part of their false and deceptive marketing, without disclosing the lack of evidence to support their conclusions.

196. Treatment guidelines and consensus statements were disseminated directly or indirectly to third-party payors and PBMs as part of the Manufacturer Defendants' deceptive marketing to formularies.

F. The Manufacturer Defendants' Misuse of Continuing Medical Education Programs to Further Their Deceptive Marketing

197. A CME is a professional education program provided to doctors. CMEs are analogous to continuing legal education programs provided to attorneys. Doctors are required to attend a certain number – and often type – of CME programs each year as a condition of licensure.

198. These programs are delivered in person (often in connection with professional organizations' conferences), online, or via written publications.

199. Doctors rely on CMEs not only to satisfy licensing requirements, but also to obtain information on new developments in medicine or to deepen their knowledge in specific areas of practice.

200. CMEs were often taught by KOLs who are highly respected in their fields, and

were thought to reflect these physicians' medical expertise, thus CMEs were especially influential with doctors.

201. The countless doctors and other health care professionals who attend or view accredited CMEs constituted an enormously important audience for opioid education.

202. As one target, the Manufacturer Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs. As a result, general practitioners were especially susceptible to the Manufacturer Defendants' deceptive marketing.

203. The Manufacturer Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the biased messages described throughout this Amended 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.

204. 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 and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[47]

205. On information and belief, physicians and others involved in health plan administration, such as pharmacy benefit managers, formulary personnel and others in

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[47] Opinion 9.0115, Financial Relationships with Industry in CME, Am. Med. Ass'n, 1 (Nov. 2011), http://www.msma.org/uploads/6/2/5/3/62530417/ama_ethical_opinion_9.0115_financial_relationships_with_industry_in_cme.doc.

Philadelphia and nationwide, attended or reviewed the Manufacturer Defendants' sponsored CMEs as the use and abuse of prescription opioids skyrocketed as alleged more fully *infra*.

206. By sponsoring CME programs provided by Front Groups like APF, AAPM and others, the Manufacturer Defendants expected instructors to deliver messages favorable to the Manufacturer Defendants, as these organizations were dependent on the Manufacturer Defendants for funding and other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct, immediate, and inherent effect on prescribers' views of opioids.

207. Producers of CMEs and the Manufacturer Defendants measured the effects of CMEs on prescribers' views on opioids, and prescribers' receptivity to and absorption of specific messages, confirming the strategic marketing purpose in supporting them and helping the Manufacturer Defendants sharpen their CME marketing campaign going forward.

G. Purdue's New Advertising Campaign that Seeks to Salvage Its Public Image While Continuing to Mislead the Public

208. Beginning in or around December 2017, Purdue placed full-page advertisements in the *New York Times* and other major newspapers that misrepresented the nature and import of purported safety measures taken by Purdue. The ads falsely claimed that the company and its products were "research-driven" and "science based." The ads utterly failed to mention Purdue's deceptive tactics for obtaining research and publications that supported its profit-driven motives, or that Purdue pleaded guilty in 2007 to "mislabeling" painkillers and paid more than $600 million in damages.

209. On July 19, 2018, Purdue placed a full-page ad in the *Washington Post* stating: "We are acutely aware of the public health risks opioid analgesics can create, even when taken as

prescribed." Only five days later, Purdue published the same ad in the same paper, omitting the phrase "when taken as prescribed."[48]

III. The Manufacturer Defendants' Widely Disseminated Misrepresentations and Omissions Created a Likelihood of Confusion or Misunderstanding as to the Safety and Efficacy of Opioids for Long-Term Use

210. The Manufacturer Defendants' marketing of opioids for long-term use to treat chronic pain, both directly and through third parties, included information that was false, deceptive, misleading, contrary to credible scientific evidence, and lacked balance and substantiation.

211. The Manufacturer Defendants' misrepresentations and omissions were part of an organized effort to penetrate the market for pain medication and convince prescribers, third-party payors, PBMs, and the public that opioids can and should be used to treat chronic pain. To this end, the Manufacturer Defendants' false and deceptive marketing materials omitted material information about the risks of opioids, and overstated their benefits. They also inaccurately suggested that long-term opioid therapy was supported by evidence, and consistently failed to disclose the lack of evidence in support of treating long-term pain with opioids.

212. These misrepresentations and omissions were specifically directed at a broad target audience that included consumers and providers such as physicians and pharmacists, as well as pharmacy benefit managers and other insurers and reimbursement professionals.

213. There are seven primary categories of false, deceptive, misleading and unfounded representations that the Manufacturer Defendants engaged in individually, collectively, and in conjunction with purportedly independent third parties. Specifically, the Manufacturer

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[48] Fred Schulte, Purdue Pharma Edits Public Service Ad in Washington Post, The Washington Post (July 24, 2018), https://www.washingtonpost.com/national/health-science/purdue-pharma-edits-public-service-ad-in-washington-post/2018/07/24/2f1ddefc-8f7c-11e8-ae59-01880eac5f1d_story.html?utm_term=.05442c556889. *Compare* https://kaiserhealthnews.files.wordpress.com/2018/07/july19_purdue.pdf *to* https://kaiserhealthnews.files.wordpress.com/2018/07/july24_purdue.pdf.

Defendants:

a. misrepresented that opioids improve effectively treat patients' pain and improve their function and quality of life;

b. downplayed the link between long-term use of opioids and addiction;

c. misrepresented that addiction risk can be effectively managed;

d. masked the signs of addiction by promoting the misleading concept of "pseudoaddiction";

e. falsely claimed that opioid withdrawal symptoms can be easily addressed;

f. misrepresented that increasing doses of opioids poses no significant additional risks of abuse, addiction, or death; and

g. overstated the risks and understated the efficacy of non-opioid based alternative pain treatments.

214. Exacerbating each of these misrepresentations or omissions was the collective effort of the Manufacturer Defendants and their Third-Party Allies to hide from the medical community material facts, including, for example, that there actually was – and is – an absence of "adequate and well-controlled studies of opioid use longer than 12 weeks."[49]

215. All of these misrepresentations and omissions, as alleged in further detail below, were false and deceptive to both ordinary consumers and the other members of the Manufacturer Defendants' target audience, including prescribers, insurers, third-party payors, PBMs and other health plan administrators. The overall impression arising from the totality of what the

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[49] Ltr. from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013), (hereinafter "Woodcock Ltr., Sept. 10, 2013"), http://docplayer.net/36264645-The-petition-requests-pertain-to-analgesia-products-therefore-this-response-is-limited-to-opioids-with-indications-for-analgesia.html.

Manufacturer Defendants said – as well as what their statements and omissions reasonably implied – created a likelihood of misunderstanding, uncertainty, and confusion regarding the safe, recommended, and medically sound therapeutic uses of opioids to treat chronic pain.

216. The Manufacturer Defendants' misrepresentations and omissions were not only likely to, but did in fact, deceive and mislead consumers, insurers, PBMs and other health plan administrators and others into believing that opioids, when used to treat chronic pain, would be beneficial to patients' health, functioning, and quality of life, and would not lead to abuse or addiction, even at increasing doses. The Manufacturer Defendants' target audience was further deceived and misled into believing that alternative, non-opioid pain treatments were inferior, ineffective, and unsafe.

217. The Manufacturer Defendants disseminated their misrepresentations directly, and indirectly through Third-Party Allies, including KOLs and Front Groups. In disseminating these misrepresentations to the Manufacturer Defendants' benefit, these Third-Party Allies, while purporting to be independent patient-advocacy and professional organizations, in fact acted at the Manufacturer Defendants' behest and direction as the Manufacturer Defendants' agents or servants within the course and scope of their agency or service. The Manufacturer Defendants accordingly are responsible for the conduct of their Third-Party Allies as alleged herein.

218. The Manufacturer Defendants failed to correct their misrepresentations and omissions and failed to instruct their Third-Party Allies to correct them. On information and belief, the Manufacturer Defendants' deceptive and misleading conduct is ongoing.

A. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Misrepresented that Prescription Opioids Improve Patients' Ability to Function and Improve their Quality of Life

219. The Manufacturer Defendants' created each of the documents and other materials (or other similar documents) outlined below to promote opioid use so that doctors would prescribe them, patients would actively seek them, and insurers and health plan administrators would approve the drugs for inclusion in – and payment or reimbursement from – private and public health plans. These materials also encouraged doctors and others to continue or approve long-term use of opioid therapy in the belief that failure to improve pain, function, or quality of life with initial doses of opioids could be overcome by increasing doses or prescribing additional short-acting opioids on an as-needed basis for breakthrough pain.

220. In addition, and as further alleged previously, the Manufacturer Defendants ignored not only that there was no evidence that opioids improved long-term functioning, but also a 2006 study of other studies that found that "[f]or functional outcomes . . . other [non-opioid] analgesics were significantly more effective than were opioids."[50]

221. As further alleged previously, studies of the use of opioids for chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. For example, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not lead patients to return to work or physical activity.[51] Moreover, users of opioids had the

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[50] Andrea D. Furlan et al., Opioids for Chronic Noncancer Pain: A Meta-Analysis of Effectiveness and Side Effects, 174(11) Can. Med. Ass'n J. 1589-1594 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

[51] BA Martell *et al.*, Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction, Annals of Internal Medicine (2007), http://annals.org/aim/article-abstract/732048/system-review-opioid-treatment-for-chronic-back-

highest increase in the number of headache days per month, scored significantly worse on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users.[52]

222. As further alleged previously, long-term use of opioids exposes users to a host of known, serious risks, including risks of misuse, abuse, addiction, overdose, and death. Chronic opioid therapy can also cause side effects, including mental clouding and confusion, sleepiness, hyperalgesia, constipation, and immune-system and hormonal problems, that degrade, rather than improve, patients' ability to function. The Manufacturer Defendants purposefully and intentionally omitted these adverse effects, as well as certain risks of drug interactions, from their publications and marketing efforts.

223. Each of the following specific statements by the Manufacturer Defendants in their deceptive marketing of opioids falsely suggests that the long-term use of opioids actually improve patients' function and quality of life, and that scientific evidence supports such claims.

224. These statements, which were directly contrary to the facts, created confusion and misunderstanding as to the purported benefits of chronic opioid therapy, and in particular the ability of opioids to improve both patients' ability to function and their quality of life. The deceptive and misleading statements influenced consumers' and others' purchasing, prescribing, and reimbursing decisions, since they were designed to convince these members of the Manufacturer Defendants' target audiences that opioids were safe and effective, and to lead them

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pain-prevalence-efficacy-association?volume=146&issue=2&page=116.; Richard Deyo *et al.*, Opioids for Low Back Pain, BMJ Publishing (Jan. 5, 2015), http://www.bmj.com/content/350/bmj.g6380.

[52] Survey: Migraine Patients Taking Potentially Addictive Barbiturate or Opioid Medications Not Approved by FDA as Migraine Treatments, (May 15, 2017), https://www.thefreelibrary.com/Survey%3A+Migraine+Patients+Taking+Potentially+Addictive+Barbiturate+or+...-a0163389345.

to choose opioids over alternative treatments and therapies for chronic pain:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy."[53] b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of long-term Kadian therapy, including physical, social, vocational, and recreational function.[54] c. Actavis distributed a product brochure and detailing document that claimed that use of Kadian to treat chronic pain would relieve "stress on your body and your mental health," allow patients to avoid "miss[ing] work," and cause patients to better enjoy their lives.[55] Government regulators warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . , results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[56] The regulators concluded that the representations were "false or misleading because they omit and minimize the serious risks associated with the drug, . . . and present unsubstantiated superiority and effectiveness claims. . . . These violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."[57] d. On information and belief, Actavis sales representatives told prescribers that prescribing Actavis' opioids would improve their patients' ability to function and improve their quality of life.

[53] *City of Chicago v. Purdue Pharma et al.*, No. 14-cv-04361 (N.D. Ill.), Third Amended Complaint at ¶ 221, Oct. 25, 2016 (Dkt. 478) (hereinafter "*Chicago v. Purdue* Third Amend. Compl., Oct. 25, 2016), http://www.feinberg.northwestern.edu/sites/ipham/conferences/globalhealthsymposium/docs/Third_Amended_Complaint_14_cv_04361.pdf.

[54] *Id.*

[55] Warning Letter from Thomas Abrams, Dir., FDA Div. of Marketing, Advertising and Communications, to Doug Boothe, CEO, Actavis U.S. (Feb. 18. 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

[56] *Id.*

[57] *Id.*

Cephalon	e. Cephalon sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."[58] Cephalon spent $150,000 to purchase copies of this book in bulk and distribute it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.[59] f. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve."[60] The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks associated with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report.[61] The publication is currently available online.[62] g. Cephalon sponsored a CME written by KOL Dr. Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 to December 15, 2008.[63] The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. h. Cephalon's 2006 marketing plan for marketing of Fentora, which was reviewed and approved at the highest levels of the company's management, was aimed at various types of pain management, including for "chronic pain patients," among other things. The marketing focus was to "generate awareness, understanding, and appropriate use of [Fentora] for breakthrough pain." A "target patient" was the patient "suffering from chronic pain."[64] i. On information and belief, Cephalon sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.
Endo	j. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."[65] Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

[58] Peter R. Wilson, Responsible Opioid Prescribing. A Clinician's Guide, Section Edition Revised & Expanded, 16:5 J Pain Medicine 1027, 1028 (May 2015) https://academic.oup.com/painmedicine/article/16/5/1027/2460527/Responsible-Opioid-Prescribing-A-Clinician-s-Guide; *Chicago v. Purdue* Third Amend Compl. at ¶ 221, Oct. 25, 2016, *supra* note 42.

[59] *Id.*

[60] Treatment Options: A Guide for People Living with Pain, American Pain Foundation, https://ce4less.com/Tests/Materials/E019Materials.pdf.

[61] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 42.

[62] Treatment Options, *supra* note 60.

[63] Lynn Webster, Optimizing Opioid Treatment for Breakthrough Pain, Medscape CME & Education (2007), https://www.medscape.org/viewarticle/563417_6.

[64] Cephalon 2006 Marketing Plan for Fentora, quoted in *U.S. v. Cephalon, Inc.*, No. 09-cv-02926 (E.D. Pa.) Fifth Amended Qui Tam Complaint at para. 66 (Sept. 13, 2013).

[65] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 42.

	k. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."[66] l. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work, for example as a chef.[67] The flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[68] m. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."[69] n. Endo provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in original).[70] *Exit Wounds* omitted warnings of the risk of interactions between opioids and benzodiazepines, which increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. o. On information and belief, Endo sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.
Janssen	p. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved, and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it easier for people to live normally."[71] The myth/fact structure implies authoritative backing for the claims, which does not exist. The targeting of older adults also ignored heightened opioid risks in this population. q. Janssen sponsored, developed, and approved content of the website *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* was financed and orchestrated by Janssen. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying that her experience would be representative of what other patients can expect to experience.[72] This video is still available today on youtube.com.[73] r. Janssen provided grants to APF to distribute to veterans the book *Exit Wounds*, which

[66] *Id.* at ¶ 221.
[67] *Id.* at ¶ 221.
[68] Warnings or limitations generally must be given equal prominence in product disclosures.
[69] Wilson, *supra* note 68; *Chicago v. Purdue* Third Amend. Compl at ¶ 221, Oct. 25, 2016, *supra* note 42.
[70] Derek McGinnis, Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families (2009).
[71] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 42.
[72] *Id.* at ¶ 221.
[73] https://www.youtube.com/user/LetsTalkPain.

	taught that opioid medications "*increase* your level of functioning" (emphasis in original).[74] *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. s. On information and belief, Janssen sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.
Purdue	t. Purdue's unbranded website *In the Face of Pain* (inthefaceofpain.com) contained testimonials from various "Advocates" who commented about opioids. One such advocate, Dr. Russell Portenoy, advocated the use of opioids because, in his words: "The negative impact of unrelieved pain on the lives of individuals . . . is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern."[75] This statement was available on inthefaceofpain.com through at least 2014 and 2015.[76] The New York Attorney General reached a settlement agreement with Purdue in 2015 regarding the misleading nature of these representations. See discussion *infra*. u. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain Vignettes." They were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, Paul, is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively.[77] v. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that "multiple clinical studies" had shown that opioids are effective in "improving daily function, psychological health, and health-related quality of life for chronic pain patients."[78] The guide is currently available online.[79] w. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve."[80] APF distributed 17,200 copies in one year alone, according to its 2007 annual report.[81] The guide is currently available online.[82] x. Purdue sponsored APF's book *Exit Wounds* (2009), which taught veterans that opioid medications "*increase* your level of functioning" (emphasis in original).[83] *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk.

[74] McGinnis, *supra* note 70.

[75] Settlement Agreement between New York Attorney General and Purdue Pharma, at pg. 7 (Aug. 19, 2015), hereinafter "NYAG-Purdue Settlement Agreement, Aug. 19, 2015"), https://ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf.

[76] *Id.* at pg. 7.

[77] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 42.

[78] A Policymaker's Guide to Understanding Pain & Its Management, American Pain Foundation, https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[79] *Id.*

[80] Treatment Options, *supra* note 60.

[81] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016 *supra* note 42.

[82] Treatment Options, *supra* note 60.

[83] McGinnis, *supra* note 70.

	y. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."[84] Purdue also spent over $100,000 to support distribution of the book.[85] z. On information and belief, Purdue sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.

225. These statements reached the Manufacturer Defendants' target audiences nationwide and in Philadelphia as intended.

B. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Failed to Disclose the Truth about the Risk of Addiction from Long-Term Opioid Use

226. The Manufacturer Defendants' failure to disclose the risks that opioids are highly addictive was central to Defendants' deceptive marketing.

227. To reach chronic pain patients, the Manufacturer Defendants and their Third-Party Allies had to overcome doctors' legitimate fears that patients would become addicted. The risk of addiction is an extremely weighty risk, condemning patients to a disease that is chronic, progressive – and, if not properly treated, often fatal. In addition, addiction recovery carries a lifetime risk of battling relapse.

228. Absent the Manufacturer Defendants' deceptive campaigns to convince doctors otherwise, it would be highly unlikely for a reasonable physician to find that the benefits from long-term opioid use for many aspects of chronic pain sufficiently outweighed the risks of addiction to justify writing the prescription.

229. Through their well-funded, widespread, and comprehensive marketing efforts, the Manufacturer Defendants and their KOLs, Front Groups and other Third-Party Allies were able

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[84] Wilson, *supra* note 68; *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 42.

[85] *Chicago v. Purdue* Third Amend. Compl. at ¶ 221, Oct. 25, 2016, *supra* note 42.

to change prescriber perceptions, despite the well-settled historical understanding and clear evidence that there is substantial risk of addiction associated with long-term opioid use.

230. The Manufacturer Defendants and their Third-Party Allies: (a) maintained that the risk of addiction for patients who take opioids long-term was low; and (b) failed to properly disclose the addiction risk as an adverse effect, even though the frequency and magnitude of the risk compelled disclosure.

231. The Manufacturer Defendants also used code words that conveyed to prescribers and patients that their product was less prone to abuse and addiction than competitors' products. For example, sales representatives for Defendants Actavis, Endo, Janssen, and Purdue promoted their drugs as having "steady-state" properties, claiming that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction.

232. Defendant Endo actively promoted its reformulated Opana ER on the basis that it was "designed to be crush-resistant," suggesting that Endo had succeeded in making the drug harder to adulterate and abuse.[86] In fact, however, the clinical significance of Endo's crush-resistant formulation or its impact on abuse and misuse has not been established for Opana ER, and Opana ER could still be ground and cut into small pieces by those looking to abuse the drug.

233. Defendant Purdue falsely suggested that OxyContin was less likely to be abused.

234. Each of the statements alleged herein was created by the Manufacturer Defendants with the expectation that, by instructing prescribers and patients that addiction rates are low, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue – APF's *A Policymaker's Guide to Understanding Pain & Its*

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[86] Endo Pharmaceuticals, Approval of a New Formulation of Opana ER Designed to be Crush Resistant, PR Newswire Association (Dec. 12, 2011), https://www.prnewswire.com/news-releases/endo-announces-fda-approval-of-a-new-formulation-of-opana-er-designed-to-be-crush-resistant-135431073.html.

Management (2011) – claimed that opioids were not prescribed often enough because of "misconceptions about opioid addiction."[87]

235. Acting directly or with and through third parties, each Manufacturer Defendant falsely claimed that the potential for addiction from opioids was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted them. For example, a 2015 literature survey found that rates of "misuse" averaged between 21% and 29%, and rates of "addiction" ranged between 8% and 12%.[88] These estimates are well in line with Purdue's own undisclosed studies, showing that between 8% and 13% of OxyContin patients became addicted,[89] but on which Purdue chose not to rely, instead citing the Porter & Jick letter as evidence of non-addiction.

236. According to the FDA, 26% of opioid patients obtain opioids from two or more prescribers, 16.5% seek early refills, and 20% use two or more pharmacies – all potential "red flags" for abuse or addiction.[90] Regulators in fact have ordered manufacturers of long-acting opioids to "[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain," in recognition of the fact that they found "high rates of

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87 Policymaker's Guide, *supra* note 78.

88 Kevin Vowles *et al.*, Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: a Systematic Review and Data Synthesis, 156 PAIN 569-76 (April 2015), https://30qkon2g8eif8wrj03zeh041-wpengine.netdna-ssl.com/wp-content/uploads/2017/12/PCSS-O-Vowles-Opioid-Use-04-11-2017.pdf. .

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

90 Len Paulozzi, M.D., Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse, https://wayback.archive-it.org/7993/20170405203727/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM233244.pdf.

addiction" in the medical literature.[91]

237. The significant and growing incidences of abuse, misuse, and addiction to opioids are also powerful evidence that the Manufacturer Defendants' statements regarding the low risk of addiction were, and are, untrue. The Manufacturer Defendants had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

238. Acting directly or through and with third parties, the Manufacturer Defendants claimed in their deceptive marketing that the potential for addiction from long-term use of opioids was relatively small or non-existent, despite the fact that the contention was false and there was no scientific evidence to support it. The Manufacturer Defendants' efforts to trivialize and conceal the potential for abuse and addiction posed by opioids were intended to deceive and mislead consumers by falsely suggesting that patients need not worry about addiction risks when using opioids for chronic pain management.

239. The Manufacturer Defendants' misrepresentations in this regard included:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction.[92] b. Actavis had a patient education brochure distributed in 2007 that claimed addiction is "less likely if you have never had an addiction problem."[93] The overall presentation suggests the risk is so low as not to be a concern. c. Kadian sales representatives told prescribers that Kadian was "steady state" and had extended-release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused.[94]

[91] September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf; Woodcock Ltr., Sept. 10, 2013, *supra* note 38.

[92] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

[93] *Id.*

[94] *Id.*

	d. Kadian sales representatives told prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused, and thereby less addictive, than other opioids.[95] e. Actavis sales representatives omitted any discussion with prescribers of addiction risks related to Kadian. In fact, a July 2010 "Dear Doctor" letter mandated by government regulators required Actavis to acknowledge to the doctors to whom it marketed its opioid drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."[96] f. On information and belief, Allergan/Actavis sales representatives omitted any discussion of addiction risks when discussing Allergan/Actavis opioid products with prescribers.
Cephalon	g. Cephalon sponsored and facilitated the development of a guidebook titled *Opioid Medications and REMS: A Patient's Guide*, which claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."[97] h. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.[98] The guide is currently available online.[99] i. On information and belief, Cephalon sales representatives omitted any discussion of addiction risks when discussing Cephalon's opioid products with prescribers.
Endo	j. On Endo's website www.opana.com, Endo claimed until at least April 2012 that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[100] The New York Attorney General investigated this statement, found that Endo had no evidence for the statement, and reached a settlement with Endo requiring corrective action.[101] See discussion *infra*. k. Similarly, Endo also provided training materials to its sales representatives stating

95 *Id.*

96 *State of Ohio v. Purdue Pharma. et al.*, Common Pleas Court, Ross County, Ohio (May 31, 2017), Complaint ¶ 40, *available at* http://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Consumer-Protection/2017-05-31-Final-Complaint-with-Sig-Page.aspx.

97 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

98 Treatment Options, *supra* note 60.

99 *Id.*

100 Settlement Agreement between New York Attorney General and Endo, at ¶ 20 (March 1, 2016) (hereinafter "NYAG-Endo Settlement Agreement, March 1, 2016"), https://ag.ny.gov/pdfs/New_York_Settlement_Agreement.pdf. .

101 *Id.* at ¶ 20.

	that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate addiction."[102] The New York Attorney General found that those statements were unwarranted. See discussion *infra*. l. Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, conveying that it was less likely to be abused. This claim was false. Government regulators warned in a May 10, 2013 letter that there was no evidence that Endo's design would "provide a reduction in oral, intranasal or intravenous abuse," and that Endo's "post-marketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." [103] m. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that "[p]eople who take opioids as prescribed usually do not become addicted."[104] The overall presentation suggests that the risk is so low as not to be a concern. The language also implies that, as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. n. Endo sponsored a website, PainAction.com, which stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."[105] o. Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult and Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients," which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients.[106] p. Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction, stating: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."[107] q. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004). It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems."[108] This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue. It is still available online today.[109] r. Endo contracted with the American Geriatrics Society ("AGS") to produce a CME promoting the 2009 Guidelines, titled *Pharmacological Management of Persistent*

[102] *Id.* at ¶ 22.
[103] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[104] *Id.*
[105] *Id.*; Joanne Zeis, Opioid Medication and Addiction, Pain Action (Oct. 2015), https://www.painaction.com/opioid-medication-addiction/.
[106] *Id.*
[107] *Id.*
[108] Endo Pharmaceuticals, Understanding Your Pain: Taking Oral Opioid Analgesics, (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.
[109] *Id.*

	Pain in Older Persons (2009). The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[110] None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug company funding to promote them after their completion. s. Endo sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.[111] t. Endo provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[112] The overall presentation suggests that the risk is so low as not to be a concern. u. On information and belief, Endo sales representatives omitted discussion of addiction risks related to Endo's opioid drugs when discussing Endo's opioid products with prescribers.
Janssen	v. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."[113] The overall presentation suggests that the risk is so low as not to be a concern. The language also implies that as long as a prescription is given, opioid use is not a problem. w. Janssen contracted with AGS to produce a CME promoting the 2009 Guidelines, titled *Pharmacological Management of Persistent Pain in Older Persons*. The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[114] The study supporting this assertion does not analyze addiction rates by age. As previously noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug-company funding to promote them after their completion. x. Janssen provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[115] The overall presentation suggests that the risk is so low as not to be

[110] Pharmacological Management of Persistent Pain in Older Persons, 57: 8 JAGS 1331-1346 (2009), https://geriatricpain.org/sites/geriatricpain.org/files/wysiwyg_uploads/ags_pharmacological_management_of_persistent_pain_in_olders_persons_2009_2.pdf.

[111] *Chicago v. Purdue* Third Amend. Compl, at ¶ 229, Oct. 25, 2016, *supra* note 42.

[112] McGinnis, *supra* note 70.

[113] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

[114] Pharmacological Management of Persistent Pain in Older Persons, *supra* note 110.

[115] McGinnis, *supra* note 70.

	a worry. y. Janssen ran a website, Prescriberesponsibly.com, which claimed that concerns about opioid addiction are "overstated."[116] z. A June 2009 Nucynta training module warned Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed."[117] aa. Janssen sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.[118] bb. Janssen sales representatives told prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to these drugs. In truth, however, as set out in Nucynta's product label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit."[119] cc. Janssen's sales representatives told prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug.[120] dd. On information and belief, Janssen sales representatives omitted discussion of addiction risks related to Janssen's opioid drugs when discussing Janssen's opioid products with prescribers.
Purdue	ee. A 2017 study funded by Purdue to analyze medical costs associated with opioid addiction noted: "[N]early 100 million Americans live with chronic pain . . . . For moderate to severe pain, opioids can provide significant symptom relief."[121] The study made no reference to the distinction in addiction risks between short-term and long-term use. ff. Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse* (2011), which under the heading "Indications of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids – skin popping, track marks, and perforated nasal septa.[122] In fact, opioid users who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use.[123] Thus, these representations deceptively reassured doctors that, as long as they do not observe those signs of

[116] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[117] *Id.*
[118] *Id.*
[119] *Id.*
[120] *Id.*
[121] Noam Kirson *et al.*, The Economic Burden of Opioid Abuse: Updated Findings, Journal of Managed Care & Specialty Pharmacy, 427 (April 2017), http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.
[122] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[123] Purdue itself acknowledged in October 2010 that OxyContin was used non-medically by injection 4-17% of the time. *See Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

	misuse, they need not be concerned that patients are abusing or addicted to opioids. gg. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that less than 1% of children prescribed opioids will become addicted.[124] The publication also asserted that pain is "undertreated" due to "misconceptions about opioid addiction." The guide is currently available online.[125] hh. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. The guide is currently available online.[126] ii. A Purdue-funded study with a Purdue co-author claimed that "evidence of the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[127] The study relied only on the Porter & Jick letter to the editor concerning a review of charts of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. The overall presentation suggests that the risk is so low as not to be a worry. jj. Purdue contracted with AGS to produce a CME promoting the 2009 Guidelines titled *Pharmacological Management of Persistent Pain in Older Persons*. The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[128] None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug company funding to promote them after their completion. Purdue trained sales representatives to target physicians treating elderly patients for conditions like osteoarthritis. In internal documents, Purdue admitted that opioids are not appropriate for the treatment of a specific disease such as osteoarthritis. kk. Purdue sponsored APF's book *Exit Wounds* (2009), which counseled veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[129] The overall presentation suggests that the risk is so low as not to be a concern. ll. Purdue sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.[130] mm. Purdue sales representatives told prescribers that Butrans has a lower abuse

[124] Policymaker's Guide, *supra* note 78.
[125] *Id.*
[126] Treatment Options, *supra* note 60.
[127] Peter Watson *et al.*, Controlled-Release Oxycodone Relieves Neuropathic Pain: A Randomized Controlled Trial in Painful Diabetic Neuropathy, 105 Pain 71 (2003), https://pdfs.semanticscholar.org/be4f/ff311b5869e11245dbc5ed433e59035d0f9c.pdf.
[128] Pharmacological Management of Persistent Pain in Older Persons, *supra* note 110.
[129] McGinnis, *supra* note 70.
[130] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

	potential than other drugs because it was essentially tamper-proof and, after a certain point, patients no longer experience a "buzz" from increased dosage.[131] nn. Advertisements that Purdue sent to prescribers stated that OxyContin ER was less likely to be favored by drug addicts, and, therefore, less likely to be abused or diverted, or result in addiction.[132] oo. Purdue sales representatives emphasized that Purdue's ER/LA opioids (OxyContin, Butrans, and Hysingla) provide slow-onset, stable doses without "peaks and valleys" – encouraging prescribers to infer that these opioids are safer because they do not produce the euphoric high that fosters addiction. In a 2011 sales training document, Purdue acknowledged that the "fewer peaks and valley" message seen in a review of sales representative call notes was "problematic" – confirming both that the statements were made and that they were false.[133] pp. On information and belief, Purdue sales representatives omitted discussion of addiction risks related to Purdue's opioid drugs when discussing Janssen's opioid products with prescribers.

240. These statements reached the Manufacturer Defendants' target audience nationwide and in Philadelphia as intended.

241. Rather than honestly disclose the risk of opioid abuse and addiction in their marketing materials, the Manufacturer Defendants and their Third-Party Allies improperly portrayed those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe long-term opioid therapy, Defendants deceptively suggested that doctors who did not treat their patients' chronic pain with opioids were failing their patients, and would potentially be subject to discipline

242. The Manufacturer Defendants and their Third-Party Allies also claimed that overblown worries about addiction caused pain to be *under-treated* and caused opioids to be

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131 *Id.*

132 *Id.*

133 *Attorney General of New Jersey v. Purdue Pharma, LP*, No. 245-17 (N.J. Super. Ct. Ch. Div. 2017), Complaint at ¶ 83; Dustin Racioppi, New Jersey Sues Drug Company Purdue Pharma in Crisis, North Jersey.Com (Oct. 31, 2017), http://www.northjersey.com/story/news/new-jersey/2017/10/31/nj-sues-another-drug-company-opioid-crisis/816924001/.

under-prescribed and over-regulated. This claim reinforced Defendants' marketing messages that the risks of addiction and abuse were exaggerated and not significant.

243. For example, Janssen's website *Let's Talk Pain* warned in a video posted online that: "[S]trict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence."[134] The program continued on to say: "Because of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients . . . . This prescribing environment is one of many barriers that may contribute to the under-treatment of pain, a serious problem in the United States."[135]

244. Similarly, a Purdue website called *In the Face of Pain*, under the heading "Protecting Access," complains that, through mid-2013, policy governing the prescribing of opioids was "at odds" with best medical practices by: (i) "unduly restricting the amounts that can be prescribed and dispensed;" (ii) "restricting access to patients with pain who also have a history of substance abuse;" and (iii) "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe."[136] This unsupported and untrue rhetoric aimed to portray doctors who did not prescribe opioids as ignoring industry best practices, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

C. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Misrepresented that Opioid Addiction Risk Can Be Avoided or Managed

245. The Manufacturer Defendants continue to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted. Presumably only to explain

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[134] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[135] *Id.*
[136] *Id.*

why doctors encounter so many patients addicted to opioids, the Manufacturer Defendants and their Third-Party Allies admit that some patients may become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. The Manufacturer Defendants claim that these tools can identify patients at high risk for addiction (stemming, for example, from personal or family histories of substance abuse or mental illness) so that doctors can more closely monitor those patients.

246. The Manufacturer Defendants' marketing claims that doctors can readily identify and manage addiction risk are not true. There is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction, and there is no scientific evidence that screening or any other precautions can remove the risk of addiction.

247. Despite the use of screening tools, patients with past substance use disorders – which every tool rates as a risk factor – receive, on average, higher doses of opioids from their physicians.

248. In addition to making deceptive representations about screening, Defendant Purdue deceptively marketed "abuse-deterrent" opioids – a reformulated version of OxyContin and Hysingla ER – in a manner that falsely implied these drugs can curb abuse and even addiction. Beginning in 2010, Purdue claimed that abuse and addiction result from "product diversion," meaning that abusers tended to snort or inject opioids rather than ingest the drugs orally. Purdue falsely assured prescribers and other members of its target audiences that its new formulation, which made its opioid pills more difficult to crush or inject, would prevent or reduce misuse, abuse, or diversion.

249. Specifically, Purdue and its sales representatives falsely claimed or implied that Purdue's abuse-deterrent formulations: (i) prevented tampering and cannot be crushed or

snorted; (ii) prevented or reduced opioid abuse, diversion, and addiction overall; and (iii) were safer than other opioids. At the same time, Purdue either failed to disclose that the abuse-deterrent formulations did not impact the most common forms of abuse – oral ingestion – or affirmatively misrepresented that most abuse is by non-oral means.[137]

250. In fact, there is no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the 2016 CDC Guideline states, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[138]

251. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations was particularly harmful because it persuaded doctors, who might otherwise curtail their opioid prescribing, to continue prescribing Purdue's opioids in the mistaken belief that they were safer. It also allowed prescribers, patients, and other members of Purdue's target audience to discount evidence of opioid addiction and attribute it to other, less safe opioids – *i.e.,* to believe that while patients might abuse or overdose on non-abuse deterrent opioids, Purdue's opioids did not carry that risk.

252. A 2014 *Evidence Report* by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain," identified "[n]o study" that had "evaluated the effectiveness of risk mitigation

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[137] *Attorney General of New Jersey v. Purdue Pharma, LP*, No. 245-17 (N.J. Super. Ct. Ch. Div. 2017), Complaint at ¶ 124; Racioppi, *supra* note 133.

[138] *CDC Guideline,* March 18, 2016, 22, *supra* note 8; *see also* Theodore J. Cicero & Matthew J. Ellis, Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin, 72(5) JAMA Psychiatry 424-430 (May 2015).

strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[139]

253. The Manufacturer Defendants' representations that the risk of addiction could be readily avoided or managed, and Purdue's representations that its abuse-deterrent formulations could help thwart addiction and abuse, were deceptive and without scientific support, as described below. These misrepresentations by the Manufacturer Defendants were intended to persuade prescribers, patients, and health care payors to choose opioid drugs over competing medications and therapies. Their marketing claims misled consumers into believing that addiction, misuse, and abuse could easily be avoided or managed. The Manufacturer Defendants' misrepresentations were not only likely to, but did in fact, influenced the purchasing and prescribing decisions of patients, doctors, and other third-party payors, by downplaying the risks associated with using opioids instead of other pain relief therapies to treat chronic pain.

254. The Manufacturer Defendants' misrepresentations included the following:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction.[140]
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."[141] The guide is currently available online.
Endo	c. Endo paid for a 2007 supplement available for CME credit in the Journal of Family Practice. This publication, titled *Pain Management Dilemmas in Primary Care: Use of Opioids*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients

[139] The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain, Agency for Healthcare Research and Quality (Sept. 19, 2014), https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/chronic-pain-opioid-treatment_research.pdf.

[140] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

[141] Treatment Options, *supra* note 60.

	at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.[142]
Purdue	d. Purdue's unbranded website *In the Face of Pain* (inthefaceofpain.com) stated that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds" with best medical practices.[143] The New York Attorney General reached a settlement agreement with Purdue in 2015 regarding the misleading nature of this website. The New York Attorney General found that the website created a false impression of impartiality and concealed that Purdue made significant financial contributions to many paid speakers whose testimonials appeared on the website.[144] See discussion *infra*. e. Purdue sponsored a CME program taught by a KOL titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes* (2012). This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.[145] f. Purdue sponsored a 2011 webinar taught by KOL Dr. Webster, titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."[146] g. On information and belief, Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction. h. On information and belief, Purdue sales representatives told prescribers that Purdue's abuse-deterrent formulations of its oral opioids OxyContin and Hysingla are more difficult to abuse and less likely to be diverted.

255. These statements reached the Manufacturer Defendants' target audience nationwide and in Philadelphia as intended.

D. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Created Confusion as to Opioid Addiction Risks by Promoting the Misleading Concept of "Pseudoaddiction"

256. The Manufacturer Defendants and their Third-Party Allies developed and

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142 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

143 *Id.*

144 NYAG-Purdue Settlement Agreement (Aug. 19, 2015), 7-8, *supra* note 64.

145 Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes, (Oct. 11, 2012), https://docmh.com/chronic-pain-management-and-opioid-use-easing-fears-managing-risks-and-improving-outcomes-pdf.

146 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

disseminated each of the following misrepresentations about "pseudoaddiction" so that, by instructing patients and prescribers that signs of addiction are actually the product of under-treated pain, doctors would prescribe more opioids to more patients and continue prescribing them, and patients would continue to use opioids despite signs of addiction.

257. The concept of "pseudoaddiction" was coined by Dr. David Haddox, who went to work for Purdue, and popularized by KOL Dr. Portenoy, who consulted for Defendants Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, blurring the line between undertreated pain and true addiction, as if patients could not experience both.

258. KOL Dr. Webster subsequently conceded that: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept."[147] Despite this partial confession, the Manufacturer Defendant continued and even increased their marketing campaign to downplay the risks of addiction.

259. Each of the Manufacturer Defendants' statements identified below falsely or deceptively states or suggests that the concept of pseudoaddiction is substantiated by scientific evidence and accurately describes the condition of undertreated patients who need, and should be treated with, higher dosages of opioids. These misrepresentations, intended to and did persuade prescribers, patients, and third-party payors to choose opioids over competing medications and therapies. In addition, the Manufacturer Defendants' deceptive marketing regarding "pseudoaddiction" influenced the purchasing and prescribing decisions of patients, doctors, and other third-party payors, and downplayed the true risks of addiction and convinced the public to

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[147] John Fauber *et al.*, Networking Fuels Painkiller Boom, Milwaukee Wisc. J. Sentinel (Feb. 19, 2012), http://bangordailynews.com/2012/02/19/health/networking-fuels-painkiller-boom/.

choose opioids over other pain relief therapies.

260. The Manufacturer Defendants' misrepresentations included the following:

Allergan/ Actavis	i. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."[148]
Cephalon	j. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding opioids are all signs of "pseudoaddiction."[149] Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.[150]
Endo	k. Endo distributed copies of a book by KOL Dr. Webster titled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents described the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as "pseudoaddiction" and that "increasing the dose in most cases . . . should be the clinician's first response."[151] l. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."[152] m. Endo trained its sales representatives to distinguish addiction from "pseudoaddiction." The New York Attorney General reached a settlement with Endo in 2016 regarding this representation and others, finding that "the 'pseudoaddiction' concept has never been empirically validated and in fact has been abandoned by some of its proponents."[153] See discussion *infra*.
Janssen	n. From 2009 to 2011, Janssen's website *Let's Talk Pain* stated that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."[154]
Purdue	o. Purdue sponsored three articles in *The Atlantic*, including an article published in 2017 written by Gerald Aronoff, M.D. entitled *Take My Pain Away . . . A Physician's Perspective of Prescription Opioids and Pain Management*, which created the impression that opioid medications were safe and effective for the treatment of chronic pain, and that newer abuse-deterrent opioid formulations were safer. This article was false and misleading. It appeared again in *The Atlantic* in 2017.

148 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
149 *Id.*
150 *Id.*
151 *Id.*
152 *Id.*
153 NYAG-Endo Settlement Agreement, (March 1, 2016), at ¶ 23, *supra* note 89.
154 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

	p. Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse* (2011), which described "pseudoaddiction" as a concept that "emerged in the literature to describe the inaccurate interpretation of [addictive drug-seeking behaviors] in patients who have pain that has not been effectively treated."[155] q. Purdue distributed to physicians, and posted on its unbranded website *Partners Against Pain,* a pamphlet titled *Clinical Issues in Opioid Prescribing* (2006). This pamphlet included a list of conduct, including "illicit drug use and deception," that it defined as indicative of "pseudoaddiction" or undertreated pain. It also stated: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."[156] r. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding opioids, are all signs of "pseudoaddiction."[157] Purdue also spent over $100,000 to support distribution of the book. s. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which stated: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."[158] The guide is currently available online.

261. These statements reached the Manufacturer Defendants' target audience nationwide and in Philadelphia as intended.

E. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Falsely Claimed that Opioid Withdrawal Symptoms Can Be Readily Managed

262. In an effort to further downplay the risks and devastating impact of addiction, the Manufacturer Defendants and their Third-Party Allies frequently claimed that physiological dependence on opioids can be adequately addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal.

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155 *Id.*

156 *Id.*

157 Wilson, *supra* note 68; *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

158 Policymaker's Guide, *supra* note 78.

263. The Manufacturer Defendants and their Third-Party Allies promoted this false and misleading message so that prescribers and patients would be more likely to initiate long-term opioid therapy and would fail to recognize the actual risk of addiction.

264. The Manufacturer Defendants failed to properly disclose that discontinuing long-term use of opioids can be very difficult. These effects make it less likely that patients will be able to stop using opioids.

265. In truth, physiological dependence on opioids starts to develop after a few days of regular use. In a report by the University of Arkansas for Medical Sciences, even a one-day opioid prescription carried a 6% risk of use at least one year later and a 2.9% risk of use at least three years later. Researchers also found that the sharpest increases in the likelihood of long-term use came at five days after the initial prescription, with another spike seen at one month.[159] Individuals given a month-long prescription were 30% likely to be using prescription opioids a year later. Common withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain, among other things.[160]

266. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to return to opioids.

267. Each of the Manufacturer Defendants' representations below falsely states or suggests that opioid withdrawal was manageable, so that physicians and users would increase opioid use.

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[159] Jessica Wapner, CDC Study Finds Opioid Dependency Begins Within A Few Days of Initial Use, Newsweek (Mar. 22, 2017), https://www.newsweek.com/cdc-opiate-addiction-572498.

[160] *See, e.g.*, Health Guide: Opiate Withdrawal, The New York Times (2013), http://www.nytimes.com/health/guides/disease/opiate-withdrawal/overview.html?mcubz=3.

268. The Manufacturer Defendants' misrepresentations, intended to persuade prescribers, patients, and third-party payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead the Manufacturer Defendants' target audience about the difficulty of treating and managing withdrawal in opioid users.

269. The Manufacturer Defendants' misrepresentations were not only likely to, but did in fact, influence the purchasing and prescribing decisions of patients, doctors, and other third-party payors.

270. The Manufacturer Defendants' deceptive marketing claims were intended to minimize the reality of managing withdrawal symptoms, and thereby encourage the public to choose opioids over other pain relief therapies and to continue taking, prescribing, or paying for opioids when used to treat long-term pain.

271. The Manufacturer Defendants' misrepresentations included the following:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to convey that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis' sales representative training also claimed that opioid withdrawal would take only a week, even in addicted patients.[161]
Endo	b. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.[162]
Janssen	c. A Janssen PowerPoint presentation used for training its sales representatives titled *Selling Nucynta ER* indicated that the "low incidence of withdraw symptoms" is a "core message" for its sales force. This message was repeated in numerous Janssen training materials between at least 2009 and 2011. The studies purportedly supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses, and would therefore not be representative of withdrawal symptoms in the patient population taking long-term opioids. Patients on long-term treatment will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied on a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use. Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window of severe withdrawal symptoms painted a misleading picture of the likelihood and severity of

[161] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[162] *Id.*

	withdrawal associated with long-term opioid therapy. Janssen also knew or should have known that patients involved in the study were not taking the drug long enough to develop rates of withdrawal symptoms comparable to withdrawal symptoms suffered by patients who use opioids for chronic pain – a use for which Janssen promoted Nucynta ER.[163] d. Janssen sales representatives told prescribers that patients on Janssen's opioid drugs were less susceptible to withdrawal than those on other opioids.[164]
Purdue	e. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use.[165] The guide is currently available online. f. Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans' low potency and its extended release mechanism.[166] g. In 2007, Purdue pled guilty to criminal charges stemming from its misleading marketing and promotion of OxyContin as having manageable withdrawal symptoms. Purdue admitted that it misrepresented to doctors that "patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug."[167] See discussion *infra*. h. On information and belief, Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be reasonably managed.

272. These statements reached the Manufacturer Defendants' target audience nationwide and in Philadelphia as intended.

F. In Their Deceptive Marketing, the Manufacturer Defendants and Their Third-Party Allies Falsely Minimized the Risks of Increasing Doses of Opioids Over Time

273. As part of their deceptive marketing campaign, the Manufacturer Defendants and their Third-Party Allies also claimed that prescribers and patients could increase doses of opioids indefinitely without added risk, even when increased doses failed to relieve pain or when doses reached levels that were "frighteningly high." The Manufacturer Defendants falsely suggested

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163 *Id.*
164 *Id.*
165 Policy Maker's Guide, *supra* note 78.
166 *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
167 Purdue Guilty Plea, (May 10, 2007), https://archive.org/stream/279028-purdue-guilty-plea/279028-purdue-guilty-plea_djvu.txt.

that patients would eventually reach a stable, effective dose as the dosage strength increased.

274. Each of the Manufacturer Defendants' misrepresentations omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

275. The Manufacturer Defendants made these misleading representations and omissions about the known risks of higher doses of opioids so that prescribers and patients would be more likely to continue to prescribe and use opioids. The misrepresentations also helped persuade physicians and patients not to discontinue opioids when patients' increased tolerance required them to seek higher doses.

276. In fact, patients that receive increasingly higher doses of opioids as part of long-term opioid therapy were three to nine times more likely to suffer an overdose than those on low doses. Compared to patients treated with non-opioid pain remedies, an opioid patient's tolerance to pain-reducing properties of opioids develops faster than tolerance to the adverse respiratory effects of opioids. Thus, continuously escalating opioid doses to respond to increased pain tolerance can lead to respiratory depression and death, even where opioids are taken as prescribed.

277. Moreover, patients are less likely to be able to terminate use of higher-dose opioids without severe withdrawal effects, leading patients to continue using opioids even when the drugs provide diminishing pain relief.[168]

278. Each of the false and deceptive representations by the Manufacturer Defendants and their Third-Party Allies downplayed the risks associated with increased doses of opioids.

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[168] It is estimated that only 11.2% of the people who need treatment for opioid addiction will actually receive it. Of the people who do receive treatment, 90% will relapse within the first year of completing a traditional treatment program. *See* https://healthresearchfunding.org/24-opiate-addiction-recovery-statistics/.

These misrepresentations were likely to, and did, confuse, deceive, and mislead the Manufacturer Defendants' target audience about the risks associated with higher doses of opioids to treat chronic pain. These misrepresentations and omissions were not only likely to, but did in fact, influence the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as the Manufacturer Defendants' misleading marketing promoted the message that patients would not be at risk if they continued to increase their doses of opioids. This misleading message influenced the Manufacturer Defendants' target audience to choose opioids over other, non-opioid treatments and medications.

279. The Manufacturer Defendants' misrepresentations included the following:

Allergan/ Actavis	i. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis' opioid, Kadian.[169]
Cephalon	j. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed.[170] The guide is currently available online. k. Cephalon sponsored a CME written by KOL Dr. Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC in 2007 and 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations, implying that opioids benefitted from less restrictive dose limitations.[171] l. On information and belief, Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.
Endo	m. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that opioids may be increased until "you are on the right dose of medication for your pain." Endo

[169] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[170] Treatment Options, *supra* note 60.
[171] Optimizing Opioid Treatment for Breakthrough Pain, *supra* note 63.

		funded the site, which was a part of Endo's marketing plan, and tracked visitors to it.[172] n. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004). It is still available online today.[173] In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief."
Janssen	o.	Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines and omitted any discussion of risks of increased doses of opioids.[174]
Purdue	p.	Through at least June 2015, Purdue's website *In the Face of Pain*, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe what – in their view – is a sufficient dose of opioids, they should find another doctor who will increase the dosage.[175] In so doing, Purdue exerted influence over prescribers who face pressure to accede to the patients' demands for increased dosages.
	q.	Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones.[176] This falsely suggested that high dose opioids are safe and appropriate. It did not disclose the risks from high dose opioids. The guide is currently available online.
	r.	Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[177] The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language failed to disclose the heightened risks at elevated doses. The guide is currently available online.
	s.	Purdue sponsored a CME issued by the American Medical Association in 2007, 2010, and 2013. The CME, titled *Overview of Pain Management Options*, was edited by KOL Dr. Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses.[178]
	t.	Purdue sales representatives told prescribers that high-dose opioids

[172] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[173] Understanding Your Pain: Taking Oral Opioid Analgesics, *supra* note 181.
[174] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[175] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[176] Policymaker's Guide, *supra* note 78.
[177] Treatment Options, *supra* note 60.
[178] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

	were effective for treating patients long-term, and omitted any discussion that increased tolerance would require increased – and increasingly dangerous – doses.[179]

280. These statements reached the Manufacturer Defendants' target audience nationwide and in Philadelphia as intended.

G. In Their Deceptive Marketing of Opioids, the Manufacturer Defendants and Their Third-Party Allies Overstated the Risks of Alternative Forms of Pain Treatment

281. The Manufacturer Defendants and their Third-Party Allies also misleadingly emphasized or exaggerated the risks of alternative therapies, such as non-opioid analgesics. These misrepresentations, which were intended to persuade prescribers, patients, and health care payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead the Manufacturer Defendants' target audience about the purported inferiority and dangers of non-opioid pain medications.

282. Further, these misrepresentations were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as the Manufacturer Defendants' misleading marketing was *specifically designed* to encourage the purchasing, prescribing, and reimbursing public to choose opioids over other pain relief therapies.

283. In overemphasizing the purported risks of non-opioid products, the Manufacturer Defendants and their Third-Party Allies routinely minimized or ignored the risks of long-term opioid therapy. These opioid risks –aside from the life-threatening risks associated with misuse, abuse, and addiction – include: hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli

[179] *Id.*

over time;"[180] hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; Neonatal Abstinence Syndrome (when an infant exposed to opioids withdraws from the drugs after birth); and potentially fatal interactions with alcohol, benzodiazepines which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions), and other drugs, among other things.

284. Despite these serious risks, the Manufacturer Defendants asserted or implied that opioids were appropriate first-line treatments and safer than alternative non-opioid treatments, including non-steroidal anti-inflammatory drugs ("NSAIDs") such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose gastrointestinal, renal, and cardiac risks, particularly for elderly patients, the Manufacturer Defendants' exaggerated descriptions of those risks were improper, and made their omissions minimizing opioid risks all the more misleading.

285. As part of this marketing ploy, the Manufacturer Defendants and their Third-Party Allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000 to 20,000 deaths annually (more than opioids), when in truth the number is closer to 3,200.[181]

286. The Manufacturer Defendants' description of NSAID risks starkly contrasted with the Manufacturer Defendants' representation of opioid risks, which, according to the Manufacturer Defendants, included mostly mild conditions such as nausea, constipation, and sleepiness (but not addiction, overdose, or death). In fact, compared with NSAIDs, opioids are

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[180] Woodcock Ltr., Sept. 10, 2013, *supra* note 38.

[181] Treatment Options, *supra* note 60, at 10; Courtney Krueger, Ask The Expert: Do NSAIDs Cause More Death than Opioids, Practical Pain Management (Nov. 2013), https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ask-expert-do-nsaids-cause-more-deaths-opioids.

responsible for approximately four times as many fatalities annually.

287. As with the Manufacturer Defendants' other misrepresentations as alleged more fully herein, the Manufacturer Defendants' misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While the volume of opioid prescriptions has exploded over the past two decades, the use of NSAIDs has declined during that same time.[182]

288. Each of the following representations by the Manufacturer Defendants and their Third-Party Allies reflects deceptive claims and omissions about the risks of opioids relative to NSAIDs:

Allergan/ Actavis	u. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs.[183] v. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, for older persons.[184] w. On information and belief, Actavis sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.
Cephalon	x. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[185] The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The guide is currently available online. y. On information and belief, Cephalon sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

[182] Joseph Mercola, Many Back Pain Treatments Are Ineffective and Unnecessary, and Here's Why, Fitness Mercola (Aug. 16, 2013), https://fitness.mercola.com/sites/fitness/archive/2013/08/16/back-pain-overtreatment.aspx.
[183] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[184] *Id.*
[185] Treatment Options, *supra* note 60.

Endo	z. Endo distributed a "case study" to prescribers titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cited an example, meant to be representative, of a patient with a "massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years).[186] The study recommended treating the patient with opioids instead. aa. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer titled *Pain: Opioid Therapy*. This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.[187] bb. Endo provided grants to APF to distribute the book *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.[188] cc. On information and belief, Endo sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.
Janssen	dd. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and 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 [in] the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness" (which the brochure claims will dissipate), and constipation.[189] ee. Janssen sponsored APF's book *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines.[190] *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.[191] ff. Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive

[186] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[187] *Id.*
[188] McGinnis, *supra* note 70.
[189] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[190] McGinnis, *supra* note 70.
[191] McGinnis, *supra* note 70.

	side effects. This statement was misleading because Nucynta is, in fact, an opioid and has the same effects as other opioids.[192] gg. On information and belief, Janssen sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.
Purdue	hh. Purdue sponsored APF's book *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.[193] ii. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[194] The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. Treatment Options also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The guide is currently available online. jj. Purdue sponsored a CME issued by the American Medical Association in 2007, 2010, and 2013. The CME, titled *Overview of Management Options*, was edited by KOL Dr. Portenoy, among others, and taught that NSAIDs, but not opioids, are unsafe at high doses.[195] kk. On information and belief, Purdue sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

289. These statements reached the Manufacturer Defendants' target audience nationwide and in Philadelphia as intended.

IV. Certain Manufacturer Defendants Admitted Their Deceptive Marketing of Opioids in Prior Guilty Pleas and Attorney General Settlements But Have Nevertheless Continued Such Practices

A. Purdue's 2007 Guilty Plea for OxyContin Marketing Misrepresentations

290. In 2007, Purdue and three top executives were indicted in Virginia and pled guilty to fraud in promoting OxyContin as non-addictive and appropriate for chronic pain.

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[192] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.
[193] McGinnis, *supra* note 70.
[194] Treatment Options, *supra* note 60.
[195] *Chicago v. Purdue* Third Amend. Compl. at ¶ 229, Oct. 25, 2016, *supra* note 42.

291. As part of its guilty plea, Purdue admitted that:

> Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:
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> * * *
>
> b. [Purdue] told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;
>
> c. [Purdue] sponsored training that 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;
>
> d. [Purdue] 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
>
> e. [Purdue] told certain 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.[196]

292. Under the plea agreement, Purdue agreed to pay $600 million in criminal and civil penalties – one of the largest settlements up to 2007 for a drug company's marketing misconduct.[197] Also, Purdue's Chief Executive Officer, General Counsel, and Chief Medical Officer pled guilty and agreed to pay a total of $34.5 million in penalties.[198]

293. Prospectively, the guilty plea and consent decree required Purdue to discontinue all deceptive marketing, including any misrepresentations regarding OxyContin's potential for abuse, addiction, or physical dependence, and to provide a fair balance of risk and benefit

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[196] Purdue Guilty Plea, *supra* note 167.
[197] *Id.*
[198] *Id.*

information.

294. Purdue's false and deceptive marketing continued even after the guilty plea and consent decree and continues to be a key factor in the current opioid epidemic in Philadelphia.

295. After the guilty plea, consent decree and penalties, rather than correct its misrepresentations and truly reform its conduct, Purdue instead built upon the deceptive messaging engaged in before which had established chronic opioid therapy as commonplace and reaped Purdue massive revenues. Since that time, and up to the present day, Purdue has both echoed the deceptions for which it was cited in 2007 and made diverse other misrepresentations in violation of the 2007 consent decree. Purdue has also continued to omit discussion of the serious risks of opioids and lack of evidence supporting long-term opioid use – thereby failing to correct its prior deceptions, to its benefit – and to affirmatively misrepresent the risks and benefits of opioids for the treatment of chronic pain, all in violation of the 2007 consent decree.

296. Purdue's post-2007 conduct, including actions of its sales force has impacted persons in the Philadelphia area.

297. Many Purdue sales representatives have operated in Philadelphia since 2007. Purdue's goal has been – and remains – that each of those representatives make in-person sales calls to multiple prescribers per day. Most of these prescribers were visited repeatedly – often monthly or even more frequently. Purdue assessed sales representatives' performance based on their ability to drive prescribing of the company's opioids; former Purdue detailers have reported having sales quotas of 500-700 OxyContin prescriptions per month.[199] On information and belief, similar sales quotas were imposed by Purdue on its sales representatives in the

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[199] *See Attorney Gen. of State of N.J. v. Purdue*, No. 245-17 (Superior Ct. of N.J., Essex County), Complaint para. 76, *at* https://www.politico.com/states/f/?id=0000015f-72ce-db7b-afff-f7de399d0001.

Philadelphia area.

298. Despite the 2007 guilty plea, and Purdue's firing of its sales force as of June 2018, on information and belief Purdue continues to disseminate false and misleading information about OxyContin and other opioids.

B. Purdue's 2015 Settlement with the New York Attorney General

299. On August 19, 2015, the New York Attorney General ("NYAG") entered into a settlement agreement with Purdue regarding Purdue's marketing of opioids.

300. In the settlement agreement, the NYAG noted that, from at least March 2014 to March 2015, the Purdue website www.inthefaceofpain.com failed to disclose that doctors who provided testimonials on the site were paid by Purdue. The NYAG concluded that Purdue's failure to disclose these financial connections misled consumers regarding the objectivity of the testimonials.

301. The settlement agreement stated, in relevant part:

> Purdue maintains an unbranded pain management advocacy website, www.inthefaceofpain.com. From March 2014 to March 2015, the website received a total of 251,648 page views. Much of the video content on www.inthefaceofpain.com is also available on YouTube. . . . .
>
> Written and video testimonials from several dozen "Advocates," whose faces appear on the website and many of whom are HCPs [health care providers], comprise a central component of the site. For example, Dr. Russell Portenoy, the recipient of almost $4,000 from Purdue for meeting and travel costs, was quoted on the website as follows: "The negative impact of unrelieved pain on the lives of individuals and their families, on the healthcare system, and on society at large is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern. Although there have been substantive improvements during the past several decades, the problem remains profound and change will require enormous efforts at many levels. Pressure from patients and the larger public is a key element in creating momentum for change."
>
> Although Purdue created the content on www.inthefaceofpain.com . . . the site creates the impression that it is neutral and unbiased. However, prior to this investigation, the website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost $231,000, for speaker programs, advisory

> meetings and travel costs, to 11 of the Advocates whose testimonials appeared on the site. The videos on YouTube also fail to disclose Purdue's payments to the Advocates.
>
> Purdue's failure to disclose its financial connections with certain Advocates has the potential to mislead consumers by failing to disclose the potential bias of these individuals.[200]

302. As part of the settlement, Purdue agreed to make certain disclosures on www.inthefaceofpain.com and its similar websites, and to pay a monetary penalty.[201]

303. Purdue's improper marketing of opioids as alleged herein continued despite this settlement. As summarized in an October 30, 2017 article in *The New Yorker*:

> Purdue has continued to fight aggressively against any measures that might limit the distribution of OxyContin, in a way that calls to mind the gun lobby's resistance to firearm regulations. Confronted with the prospect of modest, commonsense measures that might in any way impinge on the prescribing of painkillers, Purdue and its various allies have responded with alarm, suggesting that such steps will deny law-abiding pain patients access to medicine they desperately need. Mark Sullivan, a psychiatrist at the University of Washington, distilled the argument of Purdue: "Our product isn't dangerous – it's people who are dangerous."[202]

304. Further, as stated in the article, Purdue has continued to search for new users through the present, both domestically and now increasingly overseas, and in August 2015 even reportedly sought to market OxyContin to children as young as 11.[203]

C. Cephalon's 2008 Guilty Plea for Deceptive Marketing of Actiq and Subsequent Misconduct with Successor Drug Fentora

305. Cephalon continued to engage in deceptive marketing of prescription opioids, notwithstanding Cephalon's September 2008 guilty plea to misbranding and unlawful off-label

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[200] NYAG-Purdue Settlement Agreement, Aug. 19, 2015, pg. 7-8 (emphasis added), *supra* note 64.
[201] *Id.* at pg. 15-17.
[202] Patrick Radden Keefe, The Family That Built an Empire of Pain, The New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.
[203] *Id.*

marketing of its predecessor opioid drug, Actiq, the predecessor of Fentora.[204]

306. The Department of Justice noted:

> Actiq was approved for use by opioid-tolerant patients suffering from breakthrough cancer pain, that is, patients whose cancer pain was so severe that their opioid therapies (such as morphine) were no longer effective. The label called for Actiq to be prescribed by oncologists or pain specialists familiar with opioids. Yet the defendant promoted Actiq to other doctors, including general practitioners, for more general pain uses. The use of Actiq by patients who are not yet tolerant of opioids poses particular dangers.[205]

307. The DOJ further recognized: "Cephalon had its sales representatives call on doctors who would not normally prescribe the defendant's drugs in the course of the doctor's practice. Cephalon trained its sales representatives on techniques to prompt the doctors into off-label conversations. Cephalon's compensation and bonus structure encouraged off-label marketing."[206]

308. Cephalon paid a $50 million criminal fine in connection with the plea agreement. It also paid $375 million to resolve related civil proceedings.[207] In addition to admitting guilt for "profiting" by its misbranding of Actiq, Cephalon entered into a September 2008 Corporate Integrity Agreement ("CIA") and a civil settlement with the government which included as covered conduct Cephalon's off-label marketing of Actiq between January 1, 2001 and December 31, 2006.[208]

309. The CIA required Cephalon to investigate and report all conduct which could be a

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[204] *See* Guilty Plea Agreement at pg. 5, https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonguiltyplea.pdf.
[205] *See* Sentencing Memo at pg. 3, https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonsentencingmemo.pdf.
[206] *Id.* at pg. 3.
[207] *Id.* at pg. 1, 7.
[208] Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Cephalon, Inc., (Sept. 29, 2008), https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf.

probable violation of criminal, civil, or administrative laws applicable to any federal health care program and/or applicable to any legal requirements relating to the promotion of Cephalon products for which penalties or exclusion may be authorized.

310. During and after its negotiation of the Actiq guilty plea, civil settlement and CIA, Cephalon initiated and maintained an off-label marketing program for Fentora that was almost identical to the Actiq campaign for which Cephalon had pled guilty and was sanctioned, punished and prohibited from continuing.

311. Upon information and belief, Cephalon's subsequent deceptive and unlawful marketing regarding Fentora was never reported by Cephalon, as required by the CIA, thereby violating the consent decree and the CIA.

312. Since at least 2008 and up to the present, Cephalon has actively engaged in the deceptive marketing of its opioid products, despite its guilty plea and being bound by the CIA.

D. Endo's 2016 Settlement with the New York Attorney General Regarding Deceptive Marketing of Opana

313. On March 1, 2016, the NYAG entered into a settlement agreement with Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. regarding Endo's marketing and sales of Opana ER.

314. On Endo's website www.opana.com, Endo claimed until at least April 2012 that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." The NYAG found that Endo had no evidence for that statement.[209]

315. Endo also provided training materials to its sales representatives stating that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate

[209] NYAG-Endo Settlement Agreement, March 1, 2016, at ¶ 20, *supra* note 89.

addiction." The NYAG found that those statements were unwarranted.[210]

316. Endo also trained its sales representatives to distinguish addiction from "pseudoaddiction." The NYAG found that the "pseudoaddiction" concept has never been empirically validated and has been abandoned by some of its proponents, all as alleged above.[211]

317. The NYAG also noted that Endo omitted information about certain studies in its marketing pamphlets distributed to health care providers, and that Endo "omitted . . . adverse events from marketing pamphlets."[212]

318. As part of the NYAG settlement, Endo agreed to refrain from doing the following in New York: (i) "make statements that Opana ER or opioids generally are non-addictive," (ii) "make statements that most patients who take opioids do not become addicted," and (iii) "use the term 'pseudoaddiction' in any training or marketing."[213]

319. Endo also paid a $200,000 penalty in connection with the settlement.[214]

320. Endo discontinued the manufacture, marketing and sale of Opana ER after the settlement.

V. The Distributor Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls Over the Distribution of Prescription Opioids

A. The Role of Wholesale Distributors In the Pharmaceutical Supply Chain

321. The Distributor Defendants are wholesale distributors of pharmaceutical drugs.

322. Pharmaceutical distributors purchase drugs directly from manufacturers and distribute them to pharmacies, hospitals, long-term care facilities, clinics, and other health care providers, essentially acting as "middlemen." Retail pharmacies and other health care providers

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[210] *Id.* at ¶ 22.
[211] *Id.* at ¶ 23.
[212] *Id.* at ¶ 30.
[213] *Id.* at ¶ 41.
[214] *Id.* at ¶ 54.

place orders for drugs directly with the wholesale distributors who stockpile quantities of drugs in order to keep the pharmaceutical supply chain moving.

323. The Distributor Defendants operate within Pennsylvania and Philadelphia, and distribute prescription opioid drugs to pharmacies and other health care providers. As a result, the Pennsylvania Wholesale Prescription Drug Distributors License Act ("WPDDLA") requires the Distributor Defendants to register with and meet the licensing requirements of the Pennsylvania Department of Health. 63 P.S. § 391.3. The Pennsylvania Controlled Substance, Drug, Device, and Cosmetic Act ("PCSA"), 35 P.S. § 780, *et seq.*, also requires Distributor Defendants to register as distributors of controlled substances with the Commonwealth's Secretary of Health. 35 P.S. § 780-106.

324. At all relevant times, the Distributor Defendants purchased prescription opioid drugs from manufacturers, including the Manufacturer Defendants, and sold them to pharmacies and other health care providers in Pennsylvania and Philadelphia.

325. The Distributor Defendants dominate 85% of the market share for the distribution of prescription opioids. On information and belief, most or nearly all of the prescription opioids that were sold to health care providers within Pennsylvania and Philadelphia were purchased from the Distributor Defendants.

B. The Distributor Defendants' Obligations Under Pennsylvania Law and Industry Guidelines

326. While the DA does not allege a cause of action under any federal statute or regulation, Pennsylvania incorporates federal regulations and DEA interpretation for guidance with respect to its own laws and regulations.

327. The PSCA tracks and incorporates federal regulations that require the Distributor Defendants to "design and operate a system to disclose . . . suspicious orders of controlled

substances . . . Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 35 P.S. § 780-112(c) (incorporating 21 C.F.R. § 1301.74(b)).

328. Under the relevant Pennsylvania statutes, the PSCA and WPDDLA, the Distributor Defendants are required to establish effective controls against suspicious orders to prevent prescription drugs from being diverted into the community, including:

a. Maintaining detailed records of narcotics sold to pharmacies and other retail and health care providers in order to identify and track suspicious orders;

b. Reporting suspicious orders of controlled substances, including prescription opioids, to alert regulatory and law enforcement officials when it appears that prescription drugs are being diverted for illegal use; and

c. Identifying suspicious orders, based on knowledge of the legal market for narcotics, and the Distributor Defendants' unique ability to conduct due diligence.

329. The Distributor Defendants are legally required to have sufficient knowledge and understanding of the legal market for prescription narcotics and of the risks of diversion to properly control the distribution chain. To that end, the DEA instructs the Distributor Defendants and other wholesale pharmaceutical companies with respect to their responsibilities. The DEA conducts conferences to educate the Distributor Defendants and other wholesale pharmaceutical companies on the foreseeable risks of failing to properly control the distribution of controlled substances, including prescription opioids.

330. The DEA sent each of the Distributor Defendants a letter on September 26, 2006 expressly stating that a distributor has a "statutory responsibility to exercise due diligence to

avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The DEA warned the Distributor Defendants that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

331. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007, reminding them of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (**e.g.**, "excessive purchase report" or "high unity purchase") does not met the regulatory requirement to report suspicious orders. Registrants are reminded 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. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a 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. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an ordure is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as

> suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with the DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchase" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

332. The Healthcare Distribution Alliance, or HDMA, is the pharmaceutical distributors' trade association. The HDMA's industry compliance guidelines state that distributors are "[a]t the center of a sophisticated supply chain" and "are uniquely suited to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The HDMA's guidelines include recommended steps for the distributors' required due diligence: "If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."

333. Thus, under applicable legal requirements and industry guidelines, the Distributor Defendants have an affirmative, non-delegable duty to prevent the diversion of opioid drugs into Pennsylvania's communities. In addition to reporting suspicious orders, the Distributor Defendants are required to stop shipment on any order flagged as suspicious, and conduct due

diligence before shipping any order flagged as potentially suspicious to confirm that the order is not likely to be diverted.

334. The Distributor Defendants are, and are expected to be, a key link in the supply chain of prescription drugs. Under applicable statutes and regulations, distribution of prescription drugs should take place within a "closed system," intended to ensure that prescription drugs are sold solely for legal purposes, and not diverted for sale and use for illegal purposes. The Distributor Defendants have a duty and are expected to conduct due diligence into its prospective customers to determine whether they can be trusted to sell controlled substances only for lawful purposes.

335. The Distributor Defendants were on notice that controlled substances, including prescription opioid drugs, could be diverted for illegal purposes and sold for illegal purposes harmful to public health.

336. The Distributor Defendants knew that sales of prescription opioids increased rapidly in Philadelphia during the relevant time period, and continued to supply prescription opioids in dangerous quantities to retailers and health care providers in the city.

C. The Distributor Defendants Deliberately Failed To Maintain Effective Controls Over the Distribution System In Violation of Applicable Law and Industry Guidelines

337. The Distributor Defendants deliberately failed to maintain effective control over the distribution of prescription opioids in Philadelphia in order to increase their profits from sales of the drugs. They knew that excessive amounts of prescription opioids were being distributed to pharmacies and other customers in Philadelphia, and that opioids were likely to be diverted for illegal and dangerous uses.

338. In a continuous pattern of ignoring red flags, the Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal

pattern, and/or orders of unusual frequency in Philadelphia neighborhoods.

339. The Distributor Defendants supplied prescription opioids to suspicious physicians and pharmacies, allowing them to divert prescription opioids for illegal and dangerous uses.

340. The Distributor Defendants' conduct enabled the illegal diversion of opioids and resulted in the harmful effects that followed therefrom as detailed herein that has brought Philadelphia to a crisis point.

341. The Distributor Defendants have repeatedly misrepresented their compliance with their legal obligations to regulators and the public.

342. McKesson entered into a Settlement Agreement in 2008 in which it admitted failing to report suspicious orders of controlled substances to the DEA and "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to [the] DEA," but had failed in its obligations to do so. McKesson agreed to a $13.25 million civil penalty. As part of the 2008 settlement agreement, McKesson promised to no longer breach its obligations to identify and report suspicious orders of controlled substances from independent and small chain pharmacy customers. [215]

343. Despite that promise, McKesson distributed increasing amounts of prescription opioid drugs from 2008 to 2013. In January 2017, Defendant McKesson entered into another settlement agreement with the DEA, under which it paid a record $150 million fine to resolve an investigation by the U.S. Department of Justice ("DOJ").

344. The 2017 agreement stated that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the

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[215] Press Release, U.S. Department of Justice, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Prescription Drugs (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

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 usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a)." McKesson admitted that between January 2009 and the date of the Agreement, it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson further admitted that during the same time period it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers."

345. McKesson agreed that its authority to distribute controlled substances from distribution centers in Ohio, Florida, Michigan, and Colorado would be partially suspended. McKesson reported to the SEC: "The Company expects that the suspensions will not result in a supply disruption to any customer. Customers located in the distribution center service areas described above will receive controlled substances from a different distribution center during the applicable suspension periods."[216]

346. The 2017 settlement agreement is evidence that McKesson continued to breach its duties even after the 2008 settlement. Specifically, the DOJ noted in 2017 that, although McKesson developed a compliance program after the 2008 settlement, it failed to "fully implement or adhere to its own program."[217]

347. Also in 2017, McKesson agreed to pay the State of West Virginia a $20 million

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[216] McKesson Corporation, Annual Report (Form 10-K) at pg. 100 (May 12, 2015).
[217] Press Release, U.S. Department of Justice, *supra* note 215.

fine following a criminal investigation into McKesson's failure to report and half suspicious orders of prescription opioids.[218]

348. Defendant AmerisourceBergen paid a $16 million fine to the State of West Virginia in 2017 as the result of the same investigation into the Distributor Defendants' failure to report and block suspicious orders of prescription opioid pills.[219] Like McKesson, AmerisourceBergen was the subject of DEA enforcement action ten years earlier when the DEA suspended the company's licenses for some of its distribution centers. In a press release on August 27, 2007, AmerisourceBergen announced the lifting of the suspension: "AmerisourceBergen Corporation today announced that on August 25, 2007 . . . the [DEA] reinstated its Orlando Distribution Center's license to distribute controlled substances. The distribution center immediately resumed shipment of controlled substances to its customers. The license was suspended in April 2007, because DEA alleged that the distribution center had not maintained effective controls against diversion of controlled substances by retail internet pharmacies. During the suspension, the Company provided the products to its customers from another distribution center. As part of the agreement leading to the reinstatement, AmerisourceBergen implemented an enhanced and more sophisticated order monitoring program in all . . . distribution centers starting July 1, 2007 . . ."[220]

349. The $16 million fine AmerisourceBergen paid to the State of West Virginia in 2017 demonstrates that the monitoring program purportedly implemented in 2008 in order to get its licenses reinstated was ineffective. It failed utterly to prevent AmerisourceBergen from

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[218] Eric Eyre, Two Drug Distributors to Pay $36M to Settle WV Painkiller Lawsuits, Charleston Gazette-Mail (Jan. 9, 2017), https://www.wvgazettemail.com/news/health/drug-distributors-to-pay-m-to-settle-wv-painkiller-lawsuits/article_b43534bd-b020-5f56-b9f3-f74270a54c07.html.

[219] *Id.*

[220] Press Release, AmerisourceBergen Corporation, DEA Reinstates AmerisourceBergen's Orlando Distribution Center's Suspended License to Distribute Controlled Substances (Aug. 27, 2007), http://investor.amerisourcebergen.com/news-releases/news-release-details/dea-reinstates-amerisourcebergens-orlando-distribution-centers.

continuing to violate its legal obligations.

350. In light of the West Virginia investigation's findings and the massive fine incurred, a group of institutional investors in AmerisourceBergen urged the company to provide detailed information to its shareholders on management's plans to manage financial, legal, and reputational risks relating to the opioid crisis. AmerisourceBergen's board of directors urged shareholders to vote against the proposals which included independent board oversight and disclosure of information regarding executive pay "claw backs" for misconduct. At the board's urging, AmerisourceBergen's shareholders defeated the proposal.[221]

351. In 2016, Defendant Cardinal agreed to pay a $44 million fine for failure to report suspicious orders by pharmacies in three states. Cardinal's conduct violated the same federal regulations incorporated into the relevant Pennsylvania statutes. Like McKesson and AmerisourceBergen, Cardinal's multi-million dollar fine was imposed by the DOJ nearly a decade after Defendant Cardinal paid a $34 million fine to the DEA for failure to report suspicious orders of opioids.[222]

352. As substantial as those fines have been, they pale in comparison to the many billions of dollars in revenue the Distributor Defendants continue to receive from opioid sales, and have not caused the Distributor Defendants to change their conduct. Instead, the Distributor Defendants still supply quantities of prescription opioids in Philadelphia that far exceed what could be consumed for medically necessary purposes, especially given that each Defendant knows that it is not the only opioid distributor profiting on a large scale from prescription opioid

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[221] Eric Eyre, AmerisourceBergen Shareholders Reject Proposals Related to Opioid Crisis, Charleston Gazette-Mail (March 1, 2018), https://www.wvgazettemail.com/news/health/wv_drug_abuse/amerisourcebergen-shareholders-reject-proposals-related-to-opioid-crisis/article_cd0fb615-b87f-5daf-bd85-080d1caf947c.html.

[222] Press Release, U.S. Department of Justice, 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.

sales in the city.

D. The Distributor Defendants Misrepresented Their Compliance With Their Legal Obligations

353. The Distributor Defendants held themselves out to the public as law abiding wholesale drug distribution companies, even though they were not in compliance with their legal obligations, including those imposed by Pennsylvania licensing regulations.

354. The purpose of this deception was to convince the public that the Distributor Defendants were fighting the opioid epidemic in partnership with governments and public health officials.

355. All three Distributor Defendants represented in public filings with the U.S. Securities & Exchange Commission that they were in compliance with legal requirements in the years leading up to the multi-million fines they paid in 2016 and 2017.

356. In 2012, for example, AmerisourceBergen Corporation stated in its 10-K with respect to Defendant AmerisourceBergen Drug Corporation: "Wholesale distributors of controlled substances must hold valid DEA licenses, meet various security and operating standards and comply with regulations governing the sale, marketing, packaging, holding and distribution of controlled substances. The DEA, FDA and state regulatory authorities have broad enforcement powers, including the ability to suspend our distribution centers from distributing controlled substances, seize or recall products and impose significant criminal, civil and administrative sanctions. We have all necessary licenses or other regulatory approvals and believe that we are in compliance with all applicable pharmaceutical wholesale distribution requirements needed to conduct our operations."[223]

357. Also in 2012, McKesson informed its investors: "Certain of our businesses may

[223] AmerisourceBergen Corporation, Annual Report (Form 10-K), at 12 (Nov. 27, 2012).

be required to register for permits and/or licenses with, and comply with operating and security standards of the DEA , . . . various state boards of pharmacy, . . . and/or comparable state agencies . . . As part of these operating, security and licensure standards, we regularly receive requests for information and occasionally subpoenas from government authorities. Although we believe that we are in compliance in all material respects with applicable laws and regulations, there can be no assurance that a regulatory agency or tribunal would not reach a different conclusion concerning the compliance of our operations with applicable laws and regulations."[224]

358. Defendant Cardinal disclosed that the West Virginia Attorney General alleged that Cardinal "failed to maintain effective controls to guard against diversion of controlled substances in West Virginia, failed to report suspicious orders of controlled substances . . . and were negligent in distributing controlled substances to pharmacies that serve individuals who abuse controlled substances." Cardinal further stated that the company was "vigorously defending ourselves in this matter."[225]

359. After the Distributor Defendants made public statements misrepresenting their compliance with applicable laws and regulations, each entered into one or more settlement agreements with federal and state law enforcement authorities pursuant to which they paid tens of millions of dollars in fines for failing to identify and block suspicious orders of prescription opioid pills.[226]

360. The Distributor Defendants made other public statements misrepresenting the effectiveness of their monitoring and compliance systems. For example, in an interview with the Washington Post, an executive from Defendant Cardinal claimed that the company uses "advanced analytics" to monitor its supply chain, and represented that it was "as effective and

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[224] McKesson Corporation, Annual Report (Form 10-K), at 16 (May 2, 2012).
[225] Cardinal Health, Inc., Annual Report (Form 10-K), at 62 (Aug. 13, 2015).
[226] *See supra* ¶¶ 343-349.

efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[227]

361. Cardinal's sales volumes and history of violations demonstrate that the executive either misrepresented this "advanced analytics" system, or Cardinal ignored the results of the system in order to maximize profits.

362. Former CEO and Chairman of Cardinal, George Barrett, now the Executive Chairman of Cardinal's Board of Directors, testified before a committee of the U.S. House of Representatives on May 8, 2018 that Cardinal provided a "secure channel" to deliver prescription medications aided by a "constantly adaptive and rigorous system to combat controlled substance diversion."[228]

363. In the same hearing, the Chairman, President, and CEO of AmerisourceBergen Corporation testified that AmerisourceBergen "has had in place a system to monitor the orders it receives" since at least the 1980s, and represented through a detailed step-by-step description that the company has fully implemented and adhered to its own system.[229]

364. John Hammergren, Chairman, President, and Chief Executive Officer of McKesson, testified about his company's "cutting-edge controlled substances threshold management program," that purports to identify suspicious orders and report blocked orders to

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[227] Lenny Bernstein, et al., How Drugs Intended For Patients Ended Up In the Hands of Illegal Users: 'No One Was Doing Their Job', Washington Post (Oct. 22, 2016), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.751b039805c9.

[228] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 2, 4 (2018)(statement of George S. Barrett, Executive Chairman, Board of Directors, Cardinal Health, Inc.).

[229] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 2, 4 (2018)(statement of Steven H. Collis, Chairman, President, and Chief Executive Officer, AmerisourceBergen Corporation) at pg. 7-9, https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-CollisS-20180508.pdf).

federal and state authorities.[230]

365. McKesson also stated publicly in 2016 that it had a "best-in-class controlled substance monitoring program to help identify suspicious orders," and that the company is "deeply passionate about curbing the opioid epidemic in our country."[231] Like Cardinal, McKesson's history of violations and sales figures show the statement was intentionally deceptive, or McKesson ignored the system's warnings.

366. The Distributor Defendants misled the public by intentionally concealing facts that would prove the District Attorney's claims asserted here.

367. Meanwhile, the DEA's enforcement actions have been insufficient to deter the Distributor Defendants from their wrongful conduct. On information and belief, the Distributor Defendants hold multiple DEA registration numbers. When one facility is suspended, the Distributor Defendants ship controlled substances from another facility.[232]

368. The Distributor Defendants continue to fail to report or prevent the shipment of suspicious orders of prescription opioids, or otherwise take action to prevent the diversion of prescription opioids for illegal and dangerous purposes in Philadelphia.

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[230] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. 2, 4 (2018)(statement of John Hammergren, Chairman, President, and Chief Executive Officer, McKesson Corporation) at pg. 6, https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-HammergrenJ-20180508.pdf).

[231] Scott Higham, et al., Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse, Washington 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=.29838a59f594.

[232] *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion*, Hearings before the Subcommittee Oversight and Investigations, 115th Cong. (2018) (Statement of Representative Gus Bilirakis) at pg. 5, https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Transcript-20180508.pdf.

369. The Distributor Defendants' deceptive conduct has caused and contributed to the opioid crisis in Philadelphia by creating, enabling, and fueling a secondary market for prescription opioids.

VI. Defendants' False and Deceptive Marketing and Distribution of Opioids Has Been a Substantial Cause of the Current National, Regional and Philadelphia Prescription Opioid Epidemics

A. The National Prescription Opioid Epidemic

370. Starting in or about 1996 – and coinciding with a rapid increase in prescription opioid use for medical purposes as more fully set forth herein – the United States has experienced an opioid epidemic which has been characterized as the worst drug epidemic in its history. In the public health community, an epidemic is defined as a sharp increase in the prevalence of a disease (or diseases) within a discrete period of time.[233] The principal disease associated with the opioid epidemic is opioid addiction, also known as opioid use disorder.

371. Opioid addiction, like other forms of addiction, is a chronic medical condition. It is treatable. Unfortunately, for a variety of reasons, including a shortage of and limitations on private and public resources, the presence of shame and stigma, and the presence of barriers to treatment, only a small percentage of patients who need treatment actually receive the right types of treatment and levels of care, in the right settings, for the right lengths of time. In the absence of proper treatment the disease of addiction is progressive and, all too often, fatal.

372. In 2011, the CDC published an analysis of opioid use from 1999-2010 which indicated a sharp increase nationally in the prevalence of opioid addiction and opioid use disorder. The study found a 900% increase in opioid users seeking treatment for opioid addiction in the period 1999-2010. As reflected in the following graph, the sharp increase in

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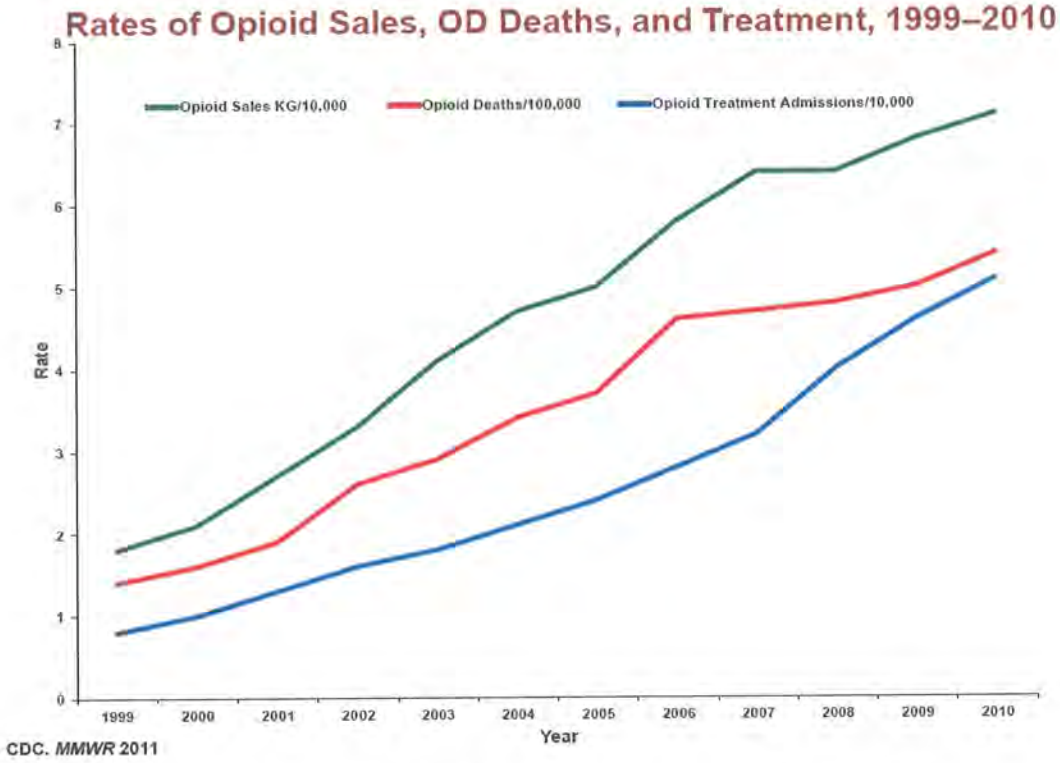
[233] Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics (2017), https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section11.html.

opioid addiction during this period has also led to a sharp increase in both fatal and non-fatal opioid overdoses, as well as other opioid-related adverse health effects (Figure 1):[234]



373. In the period 1999-2014, the CDC estimated that there were 165,000 overdose deaths in the United States associated with prescription opioid use.[235] Public health authorities estimate that, for every opioid overdose death, there are 30 non-fatal overdoses.[236] Thus, in the period 1999-2014, an estimated 5 million non-fatal opioid overdoses occurred.

374. The CDC has acknowledged the presence of an "opioid epidemic," also referred

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[234] Andrew Kolodny, M.D., Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction, at 23 (2016), http://www.pdmpassist.org/pdf/TTAC_Opioid_Policy_Research_Collaborative_20170726.pdf; Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999-2008, CDC (Nov. 4, 2011) (similar graph), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm.

[235] CDC Guideline, March 18, 2016, at pg. 2, 18, *supra* note 8.

[236] Andrea Hsu, Hospitals Could Do More for Survivors of Opioid Overdoses, Study Suggests, NPR (Aug. 22, 2017), http://www.npr.org/sections/health-shots/2017/08/22/545115225/hospitals-could-do-more-for-survivors-of-opioid-overdoses-study-suggests.

to as an "opioid overdose epidemic."[237] Similarly, a 2017 report by the U.S. Drug Enforcement Agency noted that the "opioid overdose crisis . . . is a public health and public safety emergency."[238] The U.S. Department of Health and Human Services recognized the existence of an "opioid crisis" and stated that the "United States is in the midst of a prescription opioid overdose epidemic."[239]

375. The U.S. Surgeon General also noted in 2016 that opioid use has led to an "urgent health crisis" that specifically coincided with "heavy marketing of opioids to doctors."[240] Similarly, the National Institutes of Health identified the drug industry's "aggressive marketing" as a major cause of the opioid epidemic: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*."[241]

376. On October 26, 2017, the President of the United States declared a "public health

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[237] CDC Guideline, March 18, 2016, at pg. 3, 34, *supra* note 8; *accord* CDC Press Release, CDC Launches Campaign to Help States Fight Prescription Opioid Epidemic (Sept. 25, 2017), https://www.cdc.gov/media/releases/2017/p0925-rx-awareness-campaigns.html (recognizing "opioid epidemic").

[238] Analysis of Overdose Deaths in Pennsylvania, 2016, Drug Enforcement Agency Philadelphia Division and the University of Pittsburgh, at pg. 5 (July 2017) (hereinafter "*Analysis of Overdose Deaths in Pennsylvania,* July 2017"), https://www.overdosefreepa.pitt.edu/wp-content/uploads/2017/07/DEA-Analysis-of-Overdose-Deaths-in-Pennsylvania-2016.pd_-1.pdf.

[239] Opioids: The Prescription Drug & Heroin Overdose Epidemic, U.S. Dept. of Health and Human Services (2017), https://www.hhs.gov/opioids.

[240] Opioid Crisis Message from the US General Surgeon General, (Aug. 2016), https://amersa.org/opioid-crisis-message-from-the-us-surgeon-general/ (emphasis added).

[241] America's Addiction to Opioids: Heroin and Prescription Drug Abuse (2014) (emphasis added), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

emergency" caused by opioid addiction.[242] The action allows for shifting of resources within certain government programs to help people eligible for those programs receive treatment for opioid addiction and use disorder.[243]

377. On January 10, 2018, Pennsylvania Governor Tom Wolf declared the opioid (and heroin) epidemic in Pennsylvania to be a statewide disaster and public health emergency.

B. Increases in Prescription Opioid Sales by Defendants As a Result of their False and Deceptive Marketing Were a Substantial Factor in the Current National Opioid Epidemic

378. As reflected above, over the past two decades, the rates of prescription opioid sales, opioid addiction, and opioid overdose deaths have risen together and closely track each other.

379. In 2017, the CDC noted that "[p]rescription opioid-related overdose deaths and admissions for treatment of opioid use disorder have increased in parallel with increases in opioids prescribed in the United States, which quadrupled from 1999 to 2010."[244] Similarly, it noted in 2016 that "[s]ales of opioid pain medication have increased in parallel with opioid-related overdose deaths."[245]

380. The direct correlation between increases in sales of prescription opioids and

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[242] White House Office of the Press Secretary, President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis (Oct. 26, 2017), https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis; *see also* The President's Commission on Combating Drug Addiction and the Opioid Crisis (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

[243] *Id.*

[244] Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015, at pg. 1 (July 7, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6626a4.pdf.

[245] CDC Guideline for Prescribing Opioids for Chronic Pain, The Center for Disease Control and Prevention, at pg. 2 (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

opioid addiction and overdoses prompted the CDC and other public health authorities to conclude that the unprecedented increase in the use of prescription opioids for medical purposes substantially contributed to both opioid epidemics in the period 1999-2014.[246] The CDC gathered data relating to prescription opioid usage using sales of prescription opioids as a measure of prescription opioid usage, and correlated these data with data relating to admissions for treatment of opioid use disorders and overdose deaths.

381. As can be seen from the graph *supra,* which correlates prescription opioid addiction and overdoses starting in 1999, sharp, dramatic increases in the sale of prescription opioids for medical purposes closely track sharp, substantial increases in addiction as measured by treatment admissions (as previously described) and fatal overdoses.[247]

382. Using the above data and analysis, the CDC and other researchers have concluded that the increase in prescriptions of opioid drugs for daily use to treat chronic pain substantially contributed to the epidemics in opioid addiction and overdoses.[248]

383. Public health authorities have also concluded that prescription opioid use is responsible not only for the addiction and overdose epidemics relating directly to prescription opioids, but also for the multi-year surge in non-prescription, illegal opioid use, including the use of heroin. Apparently, as law enforcement and public health authorities and the medical profession have begun to limit the improper use of prescription opioids and for other reasons (including the high price of prescription opioids), which have reduced the supply of prescription opioids for legal use, many prescription opioid users suffering from opioid addiction have turned

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246 *Id.* at pg. 2.
247 Kolodny, Jan. 12, 2015, at 560, *supra* note 7.
248 CDC Guideline, March 18, 2016, at 2, *supra* note 8.

to heroin available on the black market.[249]

384. Based on the growing weight of scientific evidence, public health experts have concluded that the current opioid epidemics of addiction and overdoses have been caused primarily by opioid pain relievers marketed and sold by Defendants and others for long-term daily use to treat chronic pain. Studies show that the vast majority of patients who die from an overdose were first exposed through prescription opioids.[250]

385. The CDC has concluded that unless and until the prescription of opioids by the medical community is reduced to appropriate levels, the current epidemics of opioid addiction and overdoses will not be contained.[251] Even then, it may take decades before the populations addicted as a result of the current opioid epidemic to be appropriately treated.

386. Chronic pain patients and others – from the users to their loved ones and communities at large – have been devastated by the prescription and use of opioids for medical uses. Some estimates of long-term prescription opioid users developing addiction are frighteningly high: one study found that between 30% and 40% of all long-term users of opioids experience problems with opioid use disorders.[252] According to the CDC, *91 Americans die*

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[249] Approximately 80% of individuals who begin using heroin made the transition from initial prescription opioids. *See* Kolodny, Jan. 12, 2015, at 560, *supra* note 7; *accord* The Mayor's Task Force to Combat the Opioid Epidemic in Philadelphia: Final Report and Recommendations, City of Philadelphia, at pg. 7 (May 19, 2017), http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf.

[250] Kolodny, Jan. 12, 2015, at pg. 563, *supra* note 7; *CDC Guidelines*, March 18, 2016, at pg. 2, *supra* note 8.

[251] Kolodny, Jan. 12, 2015, at pg. 565, *supra* note 7; *CDC Guidelines*, March 18, 2016, at pg. 2, *supra* note 8.

[252] J. Boscarino *et al.*, Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) Journal of Addictive Diseases 185 (2011); J. Boscarino *et al.*, Risk Factors for Drug Dependence Among Outpatients on Opioid Therapy in a Large US Healthcare System, 105(10) Addiction 1776 (2010).

every day from an opioid overdose.[253]

387. The opioid epidemic has led to many more overdose deaths than the heroin epidemic of the 1970s and crack cocaine epidemic of the 1980s and 1990s, prompting public health officials and commentators to conclude that the current opioid epidemic is the worst drug epidemic in U.S. history, worse than the previous heroin and crack cocaine epidemics combined.[254]

C. The City's Prescription Opioid Epidemic

388. Like the nation, the City of Philadelphia is also in the grips of a prescription opioid epidemic that has created a public health and safety emergency of unprecedented dimensions.

389. The City's public health and safety opioid emergency includes historically high incidences of opioid addiction and use disorder and of opioid-related deaths and non-fatal opioid overdoses. It also includes other adverse health effects of opioid addiction and use disorder including historically high incidences of babies born with opiate withdrawal conditions, and an unprecedented increase in new Hepatitis C infections caused by opiate injections.

390. The epidemic has also been accompanied by an unprecedented level of opioid-related emergency room visits and hospitalizations; extensive provision of emergency response services by the Fire Department and other City agencies in reviving and transporting overdose victims; and the expenditure of enormous resources by the Police Department, District Attorney's Office, Public Defender's Office, City prison system, Health Department, Department of Behavioral Health and Intellectual disability Services, Department of Human Services, and

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[253] Opioid Overdose, Understanding the Epidemic, Centers for Disease Control and Prevention, (2017), http://www.cdc.gov/drugoverdose/epidemic/index.html (emphasis added).

[254] Andrew Kolodny, M.D., Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction, at pg. 4 (2016), http://www.pdmpassist.org/pdf/TTAC_Opioid_Policy_Research_Collaborative_20170726.pdf.

other City departments and agencies providing health and related services to address increased crime and violence and family and social dysfunction linked to opioid use and addiction.

391. The Philadelphia Medical Examiner's office is struggling to keep up with a rising tide of opioid deaths and related homicides. In 2017, the homicide rate in Philadelphia reached its highest level since 2012, due in part to the opioid epidemic and competition from rival drug dealers who sell opioids. As of mid-2018, the homicide rate has already surpassed the homicide rate of 2017 by 8%.[255]

1. *The Mayor's Opioid Task Force Reports Detail the Scope of the Opioid Epidemic in Philadelphia.*

392. In 2016, in response to the opioid epidemic in the City, the City established an inter-agency and public commission, the *Mayor's Task Force to Combat the Opioid Epidemic in Philadelphia* ("Task Force"), headed by the City Health Commissioner, to investigate the opioid epidemic in Philadelphia and to make recommendations to address the ensuing public health and safety crisis. On May 19, 2017, the Task Force issued its final report and recommendations ("Final Report").[256] The Task Force has also issued two Opioid Misuse and Overdose Reports since then,[257] and further Opioid Misuse and Overdose Reports are anticipated. These Task Force reports are collectively referred to herein as the "Reports."

393. The findings of the Final Report are disturbing and alarming. The Final Report

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[255] Philadelphia Police Department: Crime Maps & Stats, https://www.phillypolice.com/crime-maps-stats/.

[256] The Mayor's Task Force to Combat the Opioid Epidemic in Philadelphia: Final Report and Recommendations, City of Philadelphia (May 19, 2017), (hereinafter "*Mayor's Task Force Report*, May 19, 2017"), http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf.

[257] Opioid Misuse and Overdose Report, Phila. Dept. of Public Health (Sept. 7, 2017), (hereinafter "*Opioids Misuse Report*, Sept. 7, 2017"), https://hip.phila.gov/Portals/_default/HIP/DataReports/Opioid/2017/Q2/OpioidMisuseOverdoseReport_Quarter2_2017_finalupdate_09122017_V2.pdf; Opioid Misuse and Overdose Report, Phila. Dept. of Public Health (Oct. 13, 2017), https://hip.phila.gov/Portals/_default/HIP/DataReports/Opioid/2017/Q2/OpioidMisuseOverdoseReport_Quarter2_2017_update_10132017.pdf.

concluded:

> The crisis caused by opioids encompasses opioid use, opioid use disorder, and related morbidity and mortality. Each of these is a problem of its own and each leads to many other individual and social problems. Opioid use and addiction are not new issues, but they have reached epidemic proportions in the city and demand a new and coordinated response.[258]

394. According to the Final Report and other sources, Philadelphia suffers a higher incidence of drug overdose deaths on a per-capita basis relative to all other counties in Pennsylvania and most large cities throughout the United States. The Final Report confirmed that Philadelphia is facing an "opioid epidemic" and "public health crisis" caused by the enormous rise in the use of prescription opioids for medical purposes.[259]

395. The City Health Department conducted a survey of Philadelphia residents in 2017 and found that "32% of Philadelphia adults surveyed – nearly 1 in 3 – used a prescription opioid in the past year."[260] According to the Final Report, the City Health Department estimates that between 100,000 and 200,000 Philadelphia residents use prescription opioids on a regular basis. Approximately 50,000 of those individuals are estimated to misuse prescription opioids.[261]

396. Regarding opioid addiction and opioid use disorder, the Final Report stated:

> The physical and psychological impact of opioid use disorder on the residents and communities of Philadelphia is difficult to measure but cannot be overstated. *Approximately 14,000 people were treated for opioid use disorder in Philadelphia's publicly funded system in the 12-month period from October 2015 through September 2016*. The patients actively seeking and participating in care still represent only a fraction of those with opioid use disorder, including those who use heroin and those in need of treatment.[262]

397. According to the Reports, in 2015, the most recent year for which such data are

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258 Mayor's Task Force Report, May 19, 2017, at pg. 6, *supra* note 224.

259 *Id.* at pg. 2 and introductory page titled "Message from Mayor Kenney."

260 Prescription Opioid and Benzodiazepine Use in Philadelphia, 2017, Phila. Dept. of Public Health (Aug. 2017), https://www.phila.gov/health/pdfs/commissioner/chart/chart%20v2e9.pdf.

261 Mayor's Task Force Report, May 19, 2017, at pg. 8, *supra* note 224.

262 *Id.* at pg. 8 (emphasis added).

available, there were 599 hospitalizations attributable to opioid poisoning in Philadelphia. That is over twice the number of hospitalizations attributable to opioid poisoning in 2002.[263] In 2017, the hospitalization rate for opioid overdoses in Philadelphia county was at 100.6 per 100,000 residents.[264] The state-wide hospitalization rate was 31 per 100,000 residents in 2017. Furthermore, as residents continue to seek out heroin in order to satisfy the addiction caused by opioid medications, the heroin hospitalization has increased at an average rate of 24% between the years of 2011 and 2016.[265]

398. Again, according to the Reports, the number of opioid overdose deaths in Philadelphia more than tripled since 2003.[266] This is consistent with the national rate, where the number of drug overdose deaths involving opioids has quadrupled since 1999.[267]

399. According to the Reports, *in Philadelphia there were a staggering 907 drug overdose deaths in 2016 alone, of which 80% were opioid-related.*[268] And, "Philadelphia is on track to record 1,200 drug overdose deaths this year (2017), a 33 percent increase over last year."[269]

400. According to a joint analysis of Pennsylvania overdose deaths by the Drug

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263 Opioids Misuse Report, Sept. 7, 2017, at pg. 18, *supra* note 225.

264 Aubrey Whelan, Pa. Hospital Admissions for Heroin Overdoses Increase Even as Pain-Med Overdoses Decline, The Philadelphia Inquirer (June 13, 2018), http://www2.philly.com/philly/health/addiction/heroin-overdoses-prescription-pain-pills-pennsylvania-hospitals-health-care-cost-20180613.html.

265 *Id.*

266 Opioids Misuse Report, Sept. 7, 2017, at pg. 25.

267 Opioid Overdose: Understanding the Epidemic, The Center for Disease Control and Prevention (2017), http://www.cdc.gov/drugoverdose/epidemic/index.html.

268 Mayor's Task Force Report, May 19, 2017, at pg. 8, *supra* note 224; *IU*, Sept. 7, 2017, at pg. 2, 25, *supra* note 225; Analysis of Overdose Deaths in Pennsylvania, July 2017, at pg. 35, 90, *supra* note 207.

269 Harold Brubaker, Drug Overdose Death Surge in Philly Continues This Year, Philadelphia Inquirer (May 16, 2017), http://www.philly.com/philly/health/addiction/drug-overdose-death-surge-continuing-this-year-20170516.html.

Enforcement Agency ("DEA") and the University of Pittsburgh, the "presence of an opioid, illicit or prescribed by a doctor, was detected in 85 percent of drug related overdose deaths in Pennsylvania in 2016."[270]

401. According to the Final Report and other sources, Philadelphia suffers a higher incidence of drug overdose deaths on a per-capita basis relative to all other counties in Pennsylvania and most large cities throughout the United States. Philadelphia was ranked first among all Pennsylvania counties in terms of the number of drug overdose deaths per 100,000 residents in 2015.[271] Philadelphia's rate of 47 drug overdose deaths per 100,000 residents was four times higher than New York City's (11 deaths per 100,000 residents) and three times higher than Chicago's (15 deaths per 100,000 residents) in 2015.[272] The vast majority of these overdose deaths were opioid related. Even more staggering, in 2015, there were more than twice as many deaths from drug overdose in Philadelphia as there were from homicide.[273] In 1999, the first year the CDC collected county numbers on overdose deaths, Philadelphia had the highest drug death rate among counties with populations of at least one million. In 1999, the rate was much lower at 18.7 per 100,000 residents.[274] This just further evidences the increase of opioid-related deaths as a result of the Defendants' deceptive marketing.

402. The drug naloxone (usually sold under the brand name Narcan) is a potentially life-saving medication that reverses the effect of opioids and is used to treat opioid overdoses that would otherwise be fatal. In 2016, Philadelphia Fire Department personnel administered

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270 Analysis of Overdose Deaths in Pennsylvania, July 2017, at pg. 5, *supra* note 207.
271 *Id.* at pg. 9.
272 *Mayor's Task Force Report*, May 19, 2017, at pg. 8, *supra* note 224.
273 The Epidemic of Overdoses from Opioids in Philadelphia, Philadelphia Department of Public Health, Vol. 1:1, 2016, https://www.phila.gov/health/pdfs/chartv1e1.pdf.
274 Larry Eichel and Meagan Pharis, Philadelphia's Drug Overdose Death Rate Among Highest in Nation, The Pew Trust (Feb. 15, 2018), https://www.pewtrusts.org/en/research-and-analysis/articles/2018/02/15/philadelphias-drug-overdose-death-rate-among-highest-in-nation.

naloxone to over 4,000 individuals, in every zip code in the City, and the Philadelphia Police Department administered naloxone to 200 individuals.[275] In addition, approximately 5,500 doses of naloxone were distributed from a needle exchange program to individuals who use drugs and are at risk of a fatal overdose.[276] Thus, in 2016, City emergency response services treated an estimated 5,000 to 10,000 opioid overdoses, a volume that was several multiples higher than the number of fatal overdoses.

403. First responders employed by the City – including police, emergency service providers, and SEPTA personnel – administered over 5,000 doses of Narcan in 2017. For every dose of Narcan administered by first responders, about ten are administered by members of the community, which works out to more than 55,000 doses. It is still not enough to prevent the overdose death rate from skyrocketing.[277]

404. The Final Report also addressed the impact of opioid use disorder on not only addicted users, but also on their families. The Final Report's conclusion was particularly distressing, stating: "Philadelphia families are burdened with grief and loss to overdose, stigma associated with opioid addiction, and the multigenerational dynamic of the disease of addiction. The consequences of alcohol and drug misuse that impact families include compromised physical health and mental health, increased health care costs, loss of productivity at school and/or work, reduced quality of life, increased crime and violence, as well as child abuse and neglect."[278]

405. All of these circumstances – opioid deaths, opioid-related emergency department

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[275] *Id.* at pg. 9.
[276] *Id.* at pg. 9.
[277] *See* Kathy Matheson, 7 Things to Know About the [Philadelphia Fire Department's] Role in Fighting the Opioids Epidemic, City of Philadelphia, https://www.phila.gov/2018-01-23-7-things-to-know-about-the-pfds-role-in-fighting-the-opioid-epidemic/.
[278] Mayor's Task Force Report, May 19, 2017, at pg. 10, *supra* note 224.

visits and hospital admissions, and drug overdoses requiring naloxone, as well as widespread, severe family and social dysfunction as discussed above – are recognized, direct, and quantifiable measures of the adverse public health and safety impact on Philadelphia due to the opioid epidemic, which was caused in substantial part by Defendants' deceptive marketing.

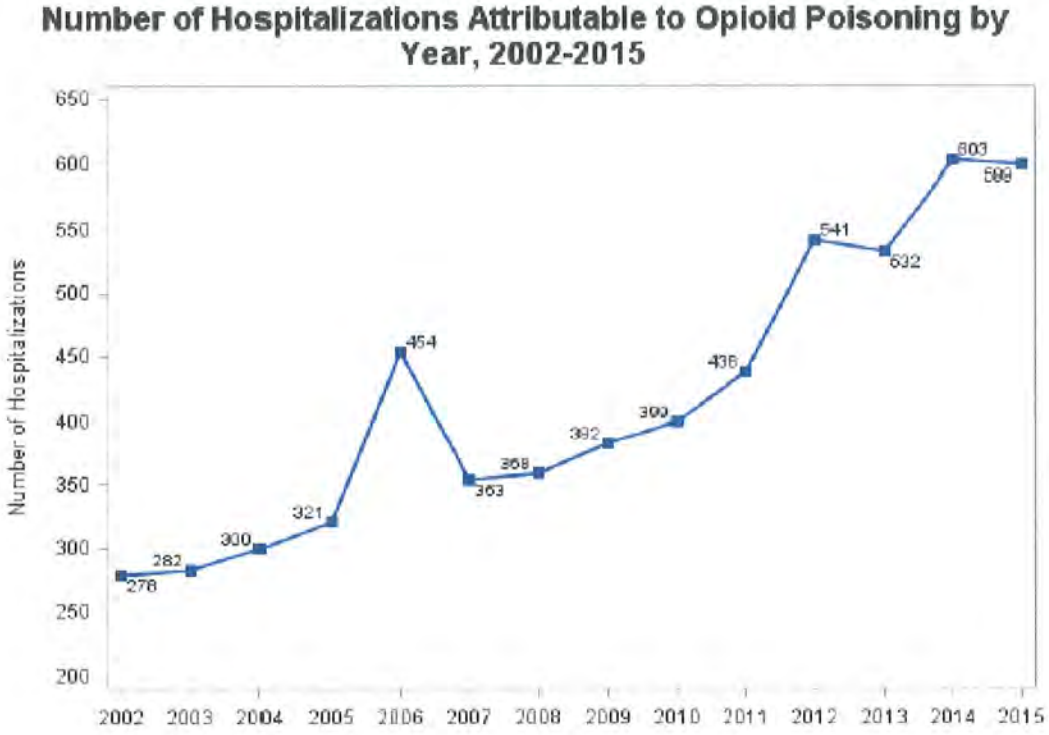
2. *Prescription Opioid Use in Philadelphia Tracks the National Pattern*

406. The opioid epidemic and public health crisis in Philadelphia closely tracks the national pattern of dramatic expansion in prescription opioid sales and resulting opioid addiction and use disorders and overdoses beginning at least as early as 2001, as alleged above.

a. Opioid Addiction and Opioid Use Disorders in Philadelphia.

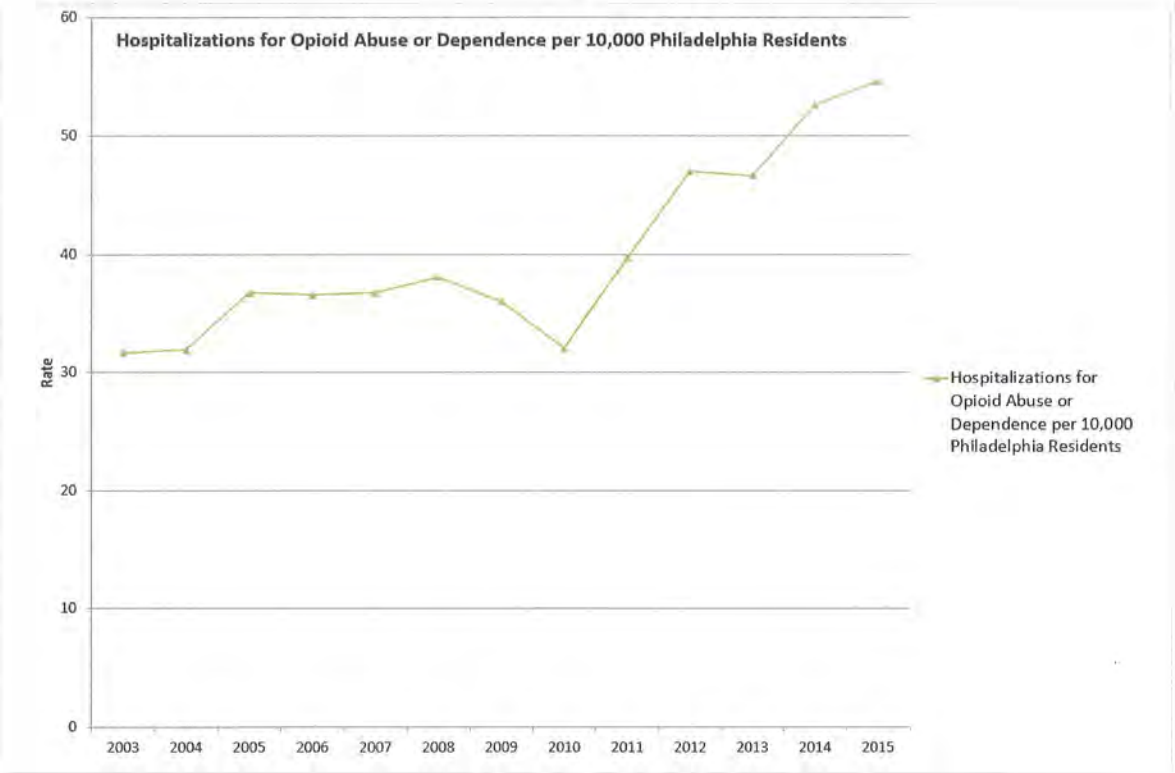
407. The City Health Department tracks the prevalence and incidence of opioid addiction and opioid use disorder in a number of ways, including referring to data collected from state authorities and data the City Health Department collects regarding hospitalization for opioid use disorder. Philadelphia data on hospitalizations attributable to opioid poisoning for the period 2002-2015 is as follows (Figure 2):[279]

[279] Opioids Misuse Report, Sept. 7, 2017, at pg. 18, *supra* note 225.



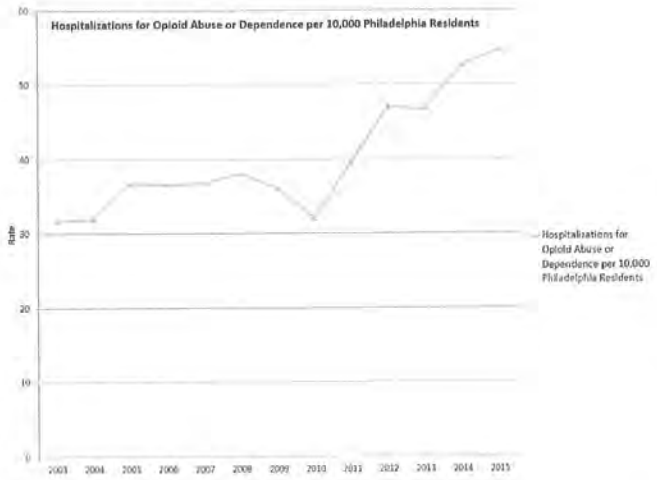
408. Similar Philadelphia data on hospitalizations for opioid abuse or dependence per 10,000 residents, for the period 2003-2015, is as follows (Figure 3):[280]

[280] Hospitalization data was gathered by the City from the Pennsylvania Health Care Cost Containment Council.

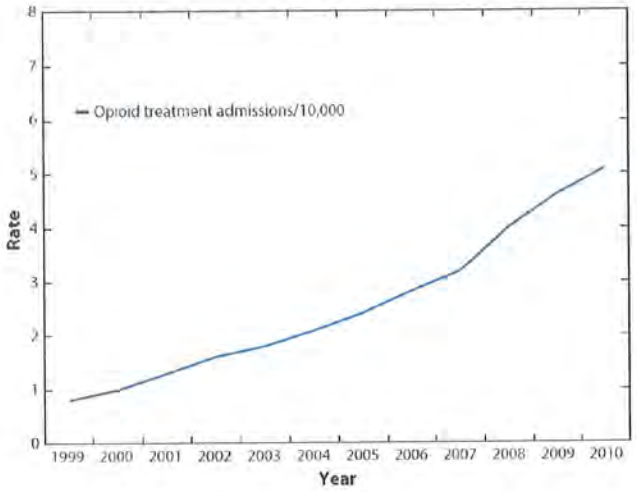


409. Hospitalization data relating to the City as referred to above are similar to the national data utilized by the CDC, and the City and national trends track each other as indicated through a comparison of the following graphs:

Philadelphia (Figure 3):[281]



Nationwide (Figure 4):[282]



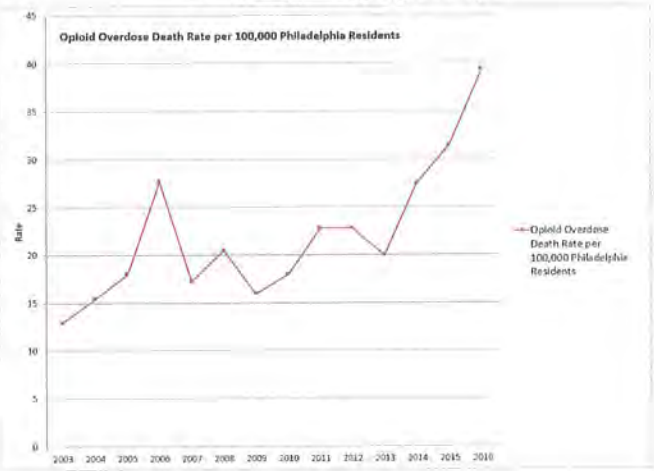
b. Opioid Overdoses in Philadelphia

410. Opioid overdose levels in Philadelphia are also similar to the national overdose levels and the City and national trends track each other as indicated in the following graphs:

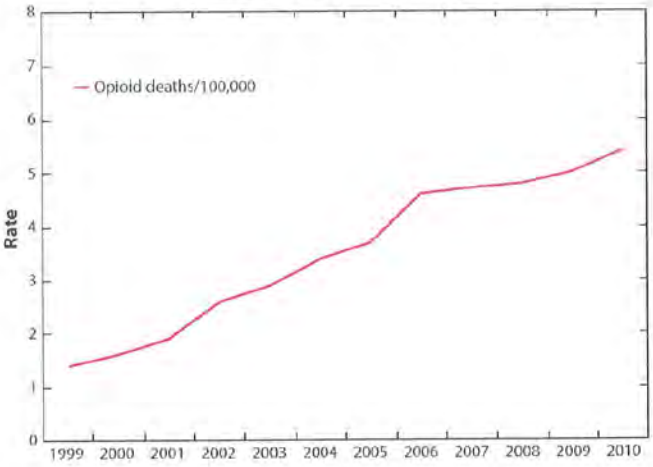
[281] Hospitalization data was gathered by the City from the Pennsylvania Health Care Cost Containment Council.

[282] This nationwide graph was extracted from Figure 1 above.

Philadelphia (Figure 5):[283]



Nationwide (Figure 6):[284]

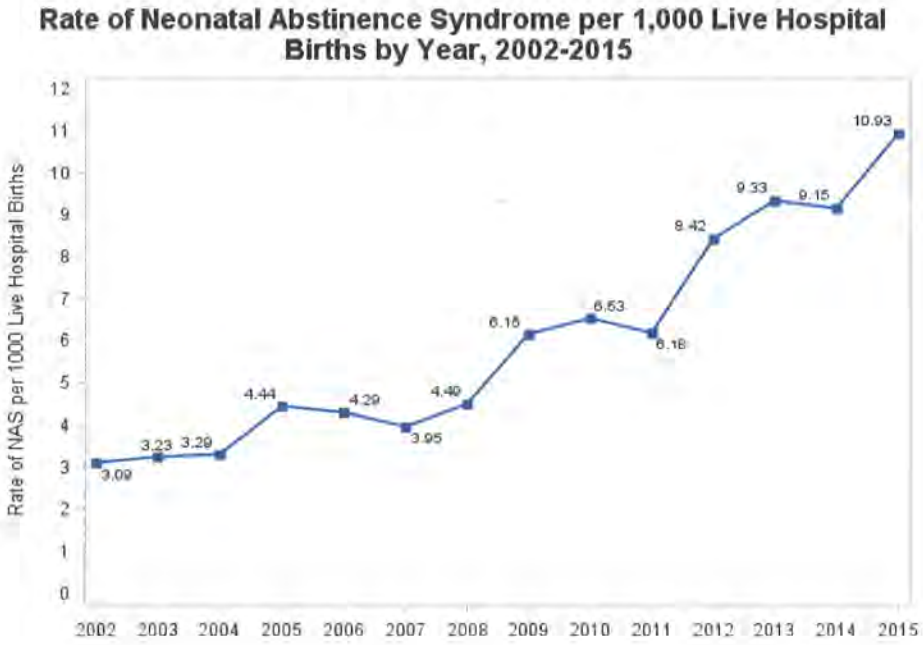


[283] Overdose data was gathered by the City from the Philadelphia Medical Examiner's Office. A similar graph of opioid overdose data based on raw numbers (*i.e.*, not adjusted to a "per 100,000 Philadelphia Residents" figure) is located in the Opioids Misuse Report, Sept. 7, 2017, at pg. 25, *supra* note 225.

[284] This nationwide graph was extracted from Figure 1 above.

c. Other Adverse Health Effects from Opioids in Philadelphia

411. Opioid use during pregnancy can lead to neonatal abstinence syndrome (NAS) and may interfere with a child's brain development and may result in subsequent consequences for mental functioning and behavior. In Philadelphia, the rate of NAS increased more than three-fold from 3 per 1,000 live births in 2002, to 11 per 1,000 live births in 2015.[285] The following graph illustrates the drastic increase in NAS in Philadelphia (Figure 7):[286]



412. Opioid use can also lead to infectious diseases such as hepatitis C virus (HCV) as a result of using needles to inject opioids.[287] If left untreated, HCV can result in liver cirrhosis, cancer, and end-stage liver disease. Incidences of HCV have increased in Philadelphia due to the

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[285] Mayor's Task Force Report, May 19, 2017, at pg. 10, *supra* note 224.
[286] Opioids Misuse Report, Sept. 7, 2017, at pg. 35, *supra* note 225.
[287] Mayor's Task Force Report, May 19, 2017, at pg. 22, *supra* note 224; *see also* Sean Murphy *et al.*, Association Between Hepatitis C Virus and Opioid Use While in Buprenorphine Treatment: Preliminary Findings (2015) ("The prevalence of hepatitis-C-virus (HCV) infections is high among opioid-dependent individuals."), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4638227/.

opioid epidemic. The Philadelphia Department of Public Health has noted that "concurrent with the increases in opioid overdose has been other adverse outcomes including increasing rates of . . . hepatitis C virus (HCV) transmission."[288] It also noted that the "number of newly-identified cases of HepC infection among 18-35 year olds nearly . . . doubled from 660 in 2010 to 1161 in 2016."[289]

413. Similarly, opioid abuse can lead to other health problems such as right-sided heart valve infections as a result of using needles to inject opioids. The incidence of right-sided heart valve infections has increased rapidly over the past decade as a consequence of the opioid epidemic.[290]

d. Use of Prescription Opioids for Medical Purposes in Philadelphia

414. Use of prescription opioids for medical purposes in the City can also be correlated with the national pattern referred to above. The CDC's analysis of opioid prescriptions reflected in the graph, *supra*, is based on data on prescriptions for opioid pain relievers collected by the U.S. Drug Enforcement Agency. Similar data are available for Philadelphia County and can be directly compared with the CDC's data on prescription use and its adverse health effects.

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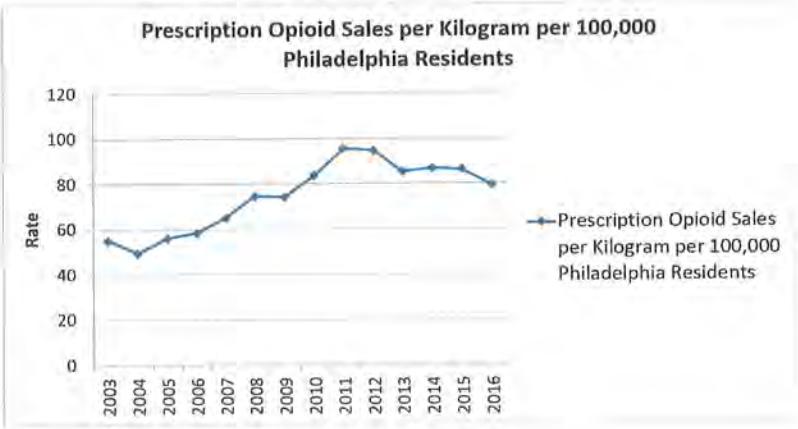
[288] Opioid Crisis Message from the US General Surgeon General, *supra* note 240.

[289] Hepatitis C Virus Infection in Philadelphia, Phila. Dept. of Public Health (Nov. 2017), http://www.phila.gov/health/pdfs/commissioner/chart/chart%20v2e11.pdf.

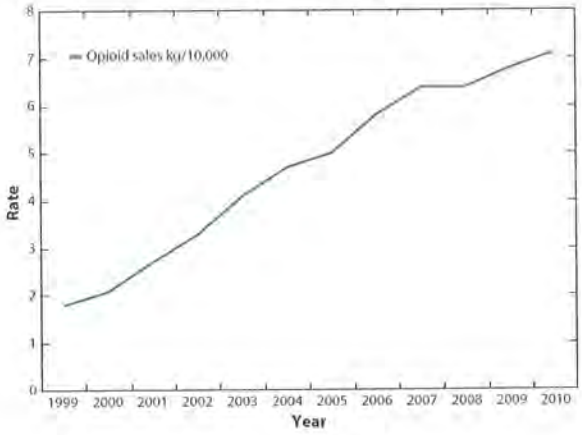
[290] M. Daubresse, *et al.*, Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013). Hospitalizations for Heart Infection Related to Drug Injection Rising Across the US, Science Daily (Sept. 1, 2016), https://www.sciencedaily.com/releases/2016/09/160901092818.htm.

415. The following graph reflects the use of prescription opioids in Philadelphia as measured by the number of prescriptions written for opioid pain relievers from 2003-2016 and compares to the national data:

Philadelphia (Figure 8):[291]



Nationwide (Figure 9):[292]



416. Just as reflected in the nationwide CDC analysis, reliable measures of prescription opioid use, opioid addiction/use disorders, and overdoses are available in Philadelphia, and the trend mirrors the national trend:[293]

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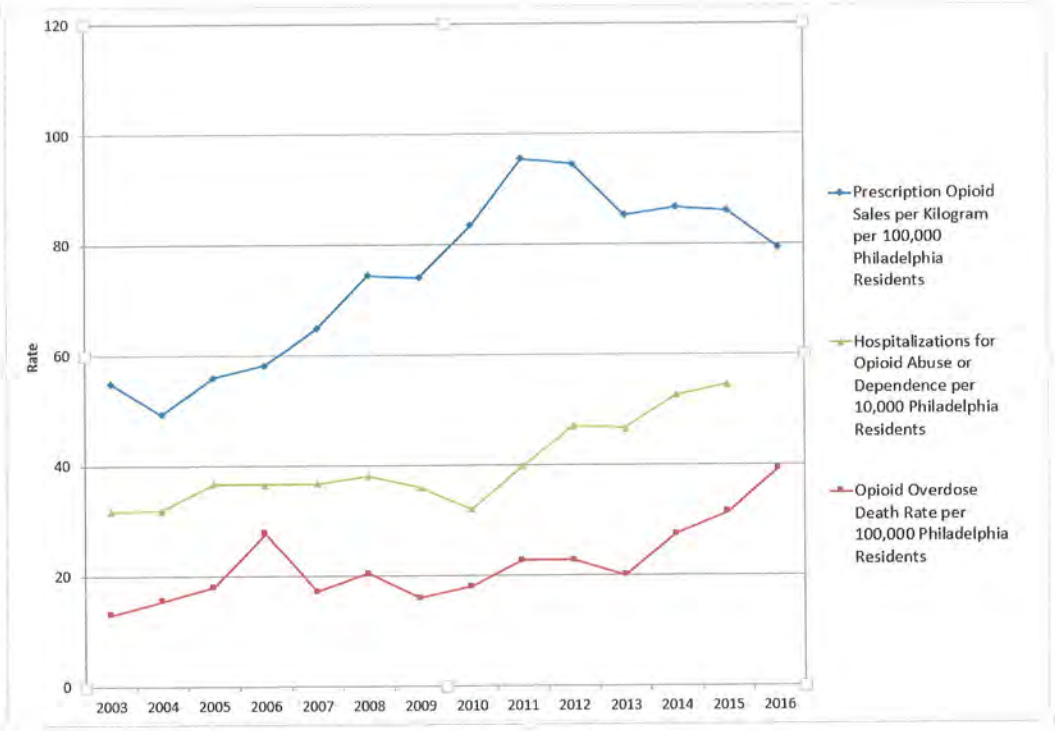
[291] Prescription opioid sales data were gathered from DEA ARCOS Retail Drug Summary Reports. A similar graph of prescription opioid sales data based on raw numbers (*i.e.*, not adjusted to a "per 100,000 Philadelphia Residents" figure) is located in the Opioids Misuse Report, Sept. 7, 2017, at pg. 5, *supra* note 225.

[292] This nationwide graph was extracted from Figure 1 above.

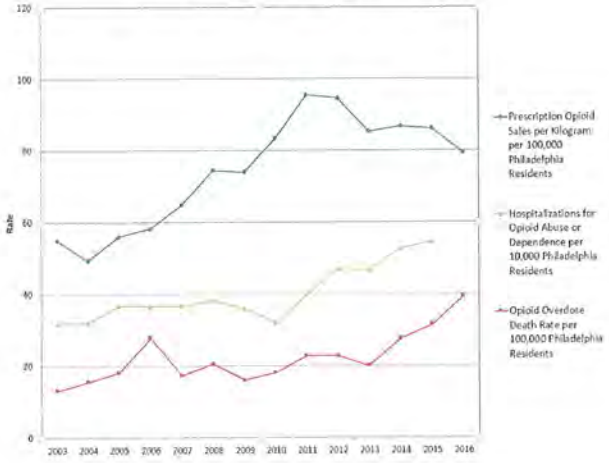
[293] Prescription opioid sales data were gathered from DEA ARCOS Retail Drug Summary Reports. Hospitalization data were gathered from the Pennsylvania Health Care Cost Containment Council. Overdose data were gathered from the Philadelphia Medical Examiner's Office.

Prescription Opioid Sales, Hospitalizations, and Overdose Deaths in Philadelphia (Figure 10):

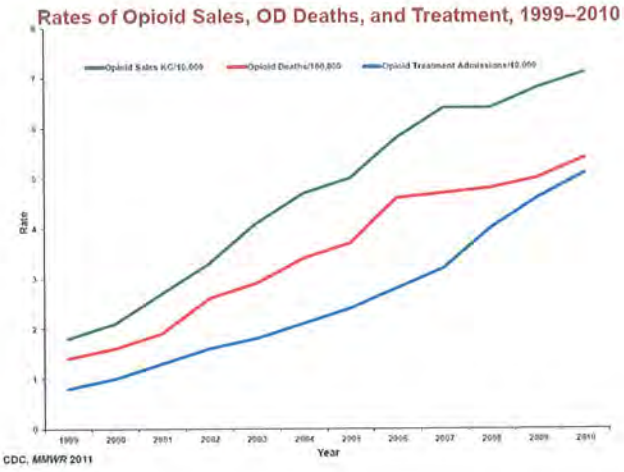


417. The parallels in patterns of morbidity and mortality for prescription opioid use in Philadelphia and nationally are striking, as noted in the following graphs:

Philadelphia (Figure 10):[294]



Nationally (Figure 1):[295]



[294] Prescription opioid sales data were gathered from DEA ARCOS Retail Drug Summary Reports. Hospitalization data were gathered from the Pennsylvania Health Care Cost Containment Council. Overdose data were gathered from the Philadelphia Medical Examiner's Office.

[295] This is a reproduction of Figure 1, *supra*.

VII. The Opioid Epidemic in Philadelphia Has Caused the City to Incur Substantial Increased Costs for Which Defendants Are Responsible

A. The City's Increased Costs of Public Medical Services Resulting from the Opioid Epidemic

418. As noted above, approximately 14,000 people were treated for opioid-use disorder in the City's publicly-funded health system during the 12-month period from October 2015 to September 2016.[296] The City incurred significant increased costs for these services during this period, as well as similar such costs for other periods. It is estimated that in 2017, opioid overdoses as a whole cost the City of Philadelphia $32 million in hospital payments alone. And as Philadelphia has the second-highest rate of opioid overdose hospitalizations in the state, this is evidence of the costly toll the City has had to endure.[297]

419. The number of persons treated actually understates the extent of opioid addiction and treatment need because patients participating in addiction treatment represent only a fraction of those with an opioid use disorder. National data establish that roughly one out of every ten people with a substance use disorder actually obtain treatment for the specific disorder.[298] Extrapolating on this basis, if there were 14,000 Philadelphia residents who received specialty treatment for an opioid use disorder, there were roughly 140,000 residents who likely needed treatment and did not seek it.[299]

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[296] Mayor's Task Force Report, May 19, 2017, at pg. 8, *supra* note 224.

[297] Aubrey Whelan, Pa. Hospital Admissions for Heroin Overdoses Increase Even As Pain-Med Overdoses Decline, The Philadelphia Inquirer (June 13, 2018), http://www2.philly.com/philly/health/addiction/heroin-overdoses-prescription-pain-pills-pennsylvania-hospitals-health-care-cost-20180613.html.

[298] Rachel Lipari *et al.*, America's Need for and Receipt of Substance Use Treatment in 2015, Substance Abuse and Mental Health Services Administration (Sept. 29, 2016), https://www.samhsa.gov/data/sites/default/files/report_2716/ShortReport-2716.html.

[299] Even that number is an undercount, because it includes only Philadelphia residents who receive treatment through the City's publicly-funded health system, and does not include others such as those residents who receive from the City private insurance or other forms of coverage and payment.

420. In Philadelphia, the nonprofit organization Community Behavioral Health ("CBH") is contracted and funded by the City of Philadelphia to manage and provide behavioral health services for Philadelphia Medicaid beneficiaries. Similarly, Philadelphia's Office of Behavioral Health manages care for uninsured Philadelphia residents.[300]

421. CBH maintains a network of treatment providers for various behavioral and medical needs, including opioid abuse. There are 13 opioid treatment providers within the CBH network ("CBH facilities"), as well as residential treatment facilities, halfway houses, hospitals, and other treatment facilities.[301] As noted, approximately 14,000 individuals who received care through the City's publicly-funded drug treatment network in 2016 received treatment for opioid-use disorders.[302] The City incurred significant costs for these City-funded and City-managed services.

422. In these CBH facilities, medication-assisted treatment with methadone is an important component of treatment for opioid-use disorder. *There are 13 methadone clinics in Philadelphia that receive City funding. In 2016, those clinics served nearly 6,000 Philadelphia residents who received methadone for their opioid use disorder.*[303] The City incurred significant costs to fund these methadone clinics. Methadone is administered daily in pill or liquid form, which costs approximately $150 per month per person.[304]

423. The availability of other forms of medication-assisted opioid treatment in the

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[300] Mayor's Task Force Report, May 19, 2017, at pg. 13, *supra* note 224.
[301] *Id.* at pg. 13.
[302] *Id.* at pg. 13.
[303] *Id.* at pg. 14.
[304] Cara Tabachnick, Breaking Good: Vivitrol, a New Drug Given as a Monthly Shot, is Helping Addicts Stay Clean, The Washington Post (March 13, 2015) ,(hereinafter "Washington Post, March 13, 2015"), https://www.washingtonpost.com/lifestyle/magazine/his-last-shot-will-a-monthly-jab-of-a-new-drug-keep-this-addict-out-of-jail/2015/03/05/7f054354-7a4c-11e4-84d4-7c896b90abdc_story.html?utm_term=.cb190c59fe30.

CBH facilities, including Suboxone (buprenorphine plus naloxone), was increased in City-funded programs in 2015 and 2016 in response to the opioid epidemic.[305] Suboxone is often administered by a daily film placed under the tongue, which costs approximately $450 per month per person.[306]

424. Another form of medication-assisted treatment, Vivitrol (injectable extended-release naltrexone), has shown early promise and is provided in City-funded programs.[307] Vivitrol is administered by a monthly injection, which costs approximately $1,000 per month per person.[308]

425. Medication-assisted treatment includes not only the medications themselves, but also psychosocial treatments. City-funded programs provide these services.

426. The City, via the Department of Behavioral Health and Intellectual Disability Services ("DBHIDS"), funded eight opioid-related substance use disorder early intervention programs in 2017. These programs target at-risk individuals in Philadelphia and provide individual, group and family therapy and service referrals.[309]

427. In direct response to the opioid epidemic, DBHIDS has taken several actions – many at considerable cost to the City – including the following:

a. Expanding the use of recovery houses and extending hours of some residential programs to accept individuals after 5 p.m. and during weekends;

b. Starting work on a web-based treatment capacity portal where all residential

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[305] Mayor's Task Force Report, May 19, 2017, at pg. 14, *supra* note 224.
[306] Washington Post, March 13, 2015, *supra* note 266.
[307] Mayor's Task Force Report, May 19, 2017, at pg. 14, 27, *supra* note 224.
[308] Washington Post, March 13, 2015, *supra* note 266.
[309] The Opioid Epidemic in Philadelphia: Implementation of the Mayor's Task Force Recommendations, at pg. 7 (Sept. 13, 2017) (hereinafter "*Implementation of Task Force Recommendations*, Sept. 13, 2017"), http://dbhids.org/wp-content/uploads/2017/04/OTF_StatusReport-1.pdf.

providers are required to enter their availability for new patients daily;

c. Authorizing higher levels of care in instances where patients face risks requiring immediate residential treatment;

d. Mandating all opioid treatment programs to offer all forms of medication-assisted treatment, including methadone, buprenorphine, and naltrexone in 2017. As a result of this mandate, naltrexone is now available in 14 outpatient treatment sites and 4 residential sites throughout Philadelphia;

e. Requiring all halfway houses to accept individuals on all forms of medication-assisted treatment and psychiatric medications, to increase patients' access to treatment; and

f. Initiating the development of a 24/7 walk-in center where individuals can receive immediate stabilization in an outpatient setting and get access to further treatment.[310]

428. The City has also incurred costs for opioid-related medical or surgical services provided to certain indigent or other qualifying residents. Such services may include treatment for infants born with NAS. Costs for treating NAS have been estimated at $60,000 per infant for hospital care alone.[311]

429. Opioid-related services also include treatment for hepatitis C virus (HCV). Recently approved treatments for HCV cost approximately $84,000 per patient.[312]

430. Approximately 80% of individuals with hospital stays in Philadelphia attributable

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[310] Mayor's Task Force Report, May 19, 2017, at pg. 12, *supra* note 224.

[311] What's Best for Babies Born to Drug-Addicted Mothers?, USA Today (April 26, 2014), https://www.usatoday.com/story/news/health/2014/04/25/best-babies-born-drug-addicted-mothers/8170555/.

[312] *Jack Hoadley et al.*, The Cost of a Cure: Revisiting Medicare Part D and Hepatitis C Drugs, (Nov. 3, 2016), http://healthaffairs.org/blog/2016/11/03/the-cost-of-a-cure-revisiting-medicare-part-d-and-hepatitis-c-drugs/.

to opioids received some form of public insurance paid by the City.[313]

431. Opioid-related deaths generally require an autopsy and toxicology screen, performed by the Philadelphia Medical Examiner's office.[314] The number of autopsies at the Medical Examiner's office has risen about 20 percent in three years, from 2,489 in 2013 to 3,018 in 2016. The increase, largely due to opioid deaths, required a doubling in the budget for supplies and materials (body bags, safety equipment, gowns, etc.) and the hiring of a new assistant medical examiner.[315] There were also increased costs for toxicology tests. These costs are funded by the City.

B. The City's Increased Costs of Emergency Services Provided by Police, Fire and EMS Resulting from the Opioid Epidemic

432. The City provides a wide range of services to protect public health and safety, including police, fire, and EMS services.

433. These City services have been severely burdened by the opioid epidemic at substantial increased costs to the City. For example, the City has faced increased expenditures for naloxone and related costs such as training EMS personnel to administer naloxone; increased volumes of 911 emergency calls and trips (so many, in fact, that the City often needs to send fire trucks because there are not enough ambulances available); increases in the number of personnel required; increases in the budget of the departments; increases in the amount of work applying for grants and other alternative sources of funding to offset increased opioid-related costs; increased turnover and recruitment costs; and increased occupational hazards arising from opioid

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313 Opioids Misuse Report, Sept. 7, 2017, at pg. 20, *supra* note 225.

314 http://www.phila.gov/health/medicalexaminer/Pathology.html; http://www.phila.gov/health/medicalexaminer/Toxicology.html.

315 Sam Wood, Victims of Opioid Overdoses Stack Up for Coroners, Costing Taxpayers Dearly, The Philadelphia Inquirer (Oct. 19, 2017), http://www2.philly.com/philly/health/addiction/bodies-opioid-ods-coroners-oxycontin-marino-trump-cdc-cadavers-philadelphia-pathologists-autopsies-norristown-toxicology-20171018.html.

use and abuse, such as accidental needle sticks and exposure to carfentanil, a powerful derivative of the synthetic opioid fentanyl. Only a few drops of carfentanil – which is 5,000 times as potent as a unit of heroin and 10,000 as potent as a unit of morphine – can be deadly.

434. The City also spends hundreds of thousands of dollars per year to purchase naloxone to address opioid overdoses. The City administered nearly 10,000 doses of naloxone in 2015 via its fire department, police department, and as part of a needle exchange program. The City pays approximately $37 per dose for naloxone. [2018 data lower – stick with this]

C. The City's Increased Public Safety Costs Resulting from the Opioid Epidemic

435. As the Task Force and others have pointed out, the opioid crisis also seriously imperils, and adversely affects, public safety in the City in a number of ways.

436. According to the Final Report, the disease of opioid addiction has prompted criminal acts by addicted individuals seeking to obtain opioids through illegal and sometimes violent means. Opioid-related crimes include, among other things, theft of money or property to finance opioid addiction; theft of prescription opioids from friends, relatives or others; and crimes committed while under the influence of opioids.

437. In 2016, there were approximately 4,000 arrests in Philadelphia related to heroin.[316] Four out of five individuals who begin using heroin start the transition to heroin from prescription opioid pain medications.[317]

438. Opioid abuse has also adversely impacted neighborhood public safety and well-being throughout the City. The notorious railroad encampment of drug users in North Philadelphia that was known as "El Campamento" is a striking example of the many ways in which the opioid problem harmed public safety in the City. Until it was shut down in the

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[316] Opioids Misuse Report, Sept. 7, 2017, at pg. 22, *supra* note 225.
[317] Mayor's Task Force Report, May 19, 2017, at pg. 7, *supra* note 224.

summer of 2017, in no small part as a result of law enforcement efforts by the City, a sprawling encampment of drug users who injected themselves with opioids and heroin in broad daylight sprung up on the railroad tracks running under Gurney Street in the Kensington area of Philadelphia. Hundreds of drug users came from around the United States to what eventually became the largest open-air drug market on the East Coast, and some of them began living near the train tracks. Piles of trash and hundreds of thousands of used needles littered the encampment.

439. In response to this enormous public health and safety crisis, the City entered into an agreement in June 2017 with Conrail, the railroad company which owns the tracks, to clean up the area. The effort, which included tearing down makeshift shacks and disposing of toxic waste, began at the end of July 2017. Ultimately, the City paid tens of thousands of dollars for security, waste removal and fencing at the Kensington encampment, plus substantial additional costs to police the area, among other things.

440. In addition, opioid use is a significant cause of homelessness in Philadelphia, and a major reason why many in the homeless population remain without shelter. Opioids frequently are abused on the City's streets, including in public parks and in municipal buildings. A large number of individuals afflicted with opioid addiction who have lost stable housing have crowded into encampments on City property, with the byproducts of their abuse – piles of trash, needles, and other waste – littering City streets. The City's homeless population has increased as a result of the opioid epidemic, and the City has taken steps to expand City-funded programs and services available to the homeless population.

441. The Task Force also noted that "improper disposal of drug use equipment," such

as used needles, poses a threat to neighborhood safety.[318] Accidental needle sticks are a safety hazard to City residents caused by the opioid epidemic.

442. Additional safety risks in the City include automobile accidents caused by impaired opioid users; child neglect, which often occurs when opioid users are unable to care for their children; and opioid-caused disturbances, which occur regularly on private and public property in the City and detract from their intended uses and value.

D. The City's Increased Policing and Criminal Justice Costs Resulting from the Opioid Epidemic

443. Opioid addiction has had major impacts on the City's policing and criminal justice system.[319] The opioid epidemic has caused an increase in crime, arrests and incarceration for opioid-related offenses.

444. As noted above, opioid-related crimes include theft of money or property to help finance opioid addiction; theft of prescription opioids from friends, relatives or others; unlawful possession or trafficking of opioids; and crimes committed while under the influence of opioids.

445. Public safety and criminal justice costs directly attributable to the opioid epidemic include increased costs for police resources, district attorney resources, public defender resources, judicial system resources, prison resources, and increased costs in the form of property losses due to crimes. Nationally, these costs have been calculated to be $7.6 billion per year for prescription opioid abuse and dependence.[320] Based on the disproportionate severity with which the opioid epidemic has impacted Philadelphia relative to the rest of the country, the City has

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[318] Mayor's Task Force Report, May 19, 2017, at pg. 23, *supra* note 224.

[319] Mayor's Task Force Report, May 19, 2017, at pg. 11, *supra* note 224; *see also* Ltr. from Nat'l Assoc. of Attorneys General to America's Health Insurance Plans, at pg. 1-2 (Sept. 18, 2017) ("State and local governments alone spend nearly 8 billion dollars a year on criminal justice costs related to opioid abuse.") (citing sources), http://www.naag.org/assets/redesign/files/sign-on-letter/Final%20NAAG%20Opioid%20Letter%20to%20AHIP.pdf.

[320] Florence, *et al.*, The Economic Burden of Opioid Overdose, Abuse, and Dependence in the United States, *2013*, Medical Care, Vol. 54, No. 10, at pg. 903 (October 2016).

suffered a disproportionate share of these financial burdens as a percentage of its population. Based on a measure of percentage of the national population alone, a rough estimate of these additional costs to the City would be approximately $30 to $40 million per year.

446. Further, the City established a "Drug Treatment Court" in 1997, which often directs criminal defendants to substance abuse disorder treatment instead of incarceration.[321] Approximately 37% of the individuals who participate in Drug Treatment Court have reported that they are opioid users. That percentage continues to increase and is currently estimated to be as much as 50%. Drug Treatment Court proceedings frequently result in individuals being enrolled in treatment services such as recovery housing, vocational training, employment placement programs, medication-assisted treatment, and trauma counseling. Over the past five years, 890 participants were accepted to Drug Treatment Court.[322] The City incurs significant costs for these programs as a direct result of the opioid epidemic.

447. The Philadelphia Department of Prisons ("PDP") has incurred increased costs for inmates incarcerated for opioid-related crimes. For example, many such inmates required additional hospitalization and medical care directly relating to their opioid addiction disorder.

448. The PDP also provides methadone and Suboxone (buprenorphine plus naloxone) to inmates who were receiving those opioid addiction treatments prior to incarceration.[323] Many inmates receive methadone in Philadelphia prisons, at a considerable cost to the City.

449. The PDP also incurs costs for medical assessments, detoxification programs, and enrollment in its cognitive behavioral therapy program related to opioid addiction. At considerable cost to the City, the PDP provides withdrawal management services to about 8,000

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[321] Mayor's Task Force Report, May 19, 2017, at pg. 11-12, *supra* note 224.
[322] *Id.* at pg. 12.
[323] *Id.* at pg. 11.

prisoners annually, approximately two-thirds to three-quarters of which are for opioids.[324]

450. Opioid addiction frequently affects released inmates. Based on the City's ongoing assessment of fallout from the opioid epidemic, there is a high correlation between prisoners released from Philadelphia prisons and subsequent overdose deaths involving opioids. In light of this risk, in 2017 the PDP began to distribute naloxone to released inmates who are at high risk of opioid abuse and overdose.[325]

E. The City's Increased Homelessness and Foster Care Costs Resulting from the Opioid Epidemic

451. The City, via its Department of Behavioral Health, increased the capacity of the City's "Housing First/Pathways to Housing" program in 2017 by adding 60 slots targeting individuals with opioid-use disorder.[326] The City incurs costs of $28,500 per year for each slot, including housing, medical treatment, psychiatric care, and social services,[327] at a total annual cost of approximately $1.7 million per year ($28,500 x 60) for this program which arises directly from the opioid epidemic.

452. The City has incurred increased costs for homelessness stemming from opioid addiction. The City secures both temporary and longer-term housing for the City's homeless, including for homeless individuals addicted to opioids. The City also provides certain health care and other services for the homeless. The City's Office of Homeless Services operated with a $45 million budget in 2016,[328] some of which was used to serve opioid-addicted homeless. The opioid crisis has hit lower-income Philadelphians the hardest. The rate at which these individuals

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[324] *Id.* at 11.
[325] Implementation of Task Force Recommendations, Sept. 13, 2017, at pg. 9, *supra* note 271.
[326] *Id.* at 7.
[327] Don Sapatkin, In Philly, Finding a Place for the Homeless on Opioids, The Philadelphia Inquirer (Sept. 29, 2017), http://www.philly.com/philly/health/addiction/housing-first-treatment-second-philadelphia-pathways-for-homeless-opioid-users-20170929.html.
[328] The Mayor's Operating Budget in Brief for Fiscal Year 2018, at pg. 71 (March 2017), http://www.phila.gov/finance/pdfs/FY18-22%20Budget%20in%20Brief_ALL.pdf.

visited Philadelphia hospitals for opioid overdoses was nearly double the state-wide rate in 2016 and 2017.[329] Whatever limited resources the City had been using to provide shelter to those that are homeless are now spread even thinner as a result of this addiction, and its effect upon a vulnerable population.

453. The City also incurs costs to fund its foster care system. Opioid abuse has led to an increase in foster care services and attendant costs due to the prevalence of parents struggling with opioid addiction. For example, in one nearby state (Ohio), "[h]alf of the state's foster-care population is made up of children with opioid-addicted parents."[330] In Philadelphia, the City pays a $21.25 per diem rate ($7,756 per year) to foster parents to cover expenses such as food, clothing, school supplies, transportation, and other incidentals for the child.[331] The City's foster care costs have increased significantly as a direct result of the opioid epidemic.

F. The City's Increased Public Awareness Costs Resulting from the Opioid Epidemic

454. The City granted a $1.9 million budget allocation to the Philadelphia Department of Public Health ("DPH") for fiscal 2018 (7/1/17 – 6/30/18) for the ongoing funding of a program targeting the opioid crisis.[332] The funds are being used to increase public awareness about the dangers of prescription opioids; attempt to reduce or narrow opioid prescribing through a campaign aimed at the highest-prescribing health care providers; improve the distribution and

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[329] Aubrey Whelan, Pa. Hospital Admissions for Heroin Overdoses Increase Even As Pain-Med Overdoses Decline, The Philadelphia Inquirer, (June 13, 2018), http://www2.philly.com/philly/health/addiction/heroin-overdoses-prescription-pain-pills-pennsylvania-hospitals-health-care-cost-20180613.html.

[330] Esme Deprez, The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry, Bloomberg Businessweek (Oct. 5, 2017), https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.

[331] City of Philadelphia Five Year Financial and Strategic Plan for Fiscal Years 2018-2022, at 160 (March 2, 2017), http://www.phila.gov/finance//pdfs/FY18-22-Five-Year-Plan.pdf.

[332] The Mayor's Operating Budget in Brief for Fiscal Year 2018, at pg. ii (March 2017), https://www.phila.gov/media/20170301200611/FY18-22-Five-Year-Plan.pdf. .

use of naloxone; and develop a real-time database to track openings in addiction treatment facilities.[333]

455. At considerable cost, the City, via DPH, launched a website (www.donttaketherisk.org) in May 2017 aimed at raising awareness of the dangers of opioids.[334]

456. At considerable cost, the City, via DPH and DBHIDS, mailed opioid prescribing guidelines to 16,000 health care providers in Southeastern Pennsylvania in 2017 to educate health care professionals about responsible opioid prescribing.[335]

457. At considerable cost, the City, via DPH, launched a detailing program in 2017 in which 1,400 health care providers across Philadelphia received one-on-one guidance on how to prescribe opioids judiciously. Leadership from DPH and DBHIDS visited all major health systems serving adult patients in Philadelphia and is working with them to reduce overprescribing of prescription opioids. The City's campaign was "Think NSAIDs," which emphasized the use of non-opioid pain treatments. DPH representatives also distributed guidelines on prescribing and tapering opioids. The campaign began in November 2017, ran for 8 weeks, and cost approximately $290,000 to administer.[336]

G. The City Increased Prescription Drug, Health Care, and Disability Costs for its Employees Resulting from the Opioid Epidemic

458. In addition to the many social services costs set forth above, the City has spent significant amounts of money each year for purchases of prescription opioids (and related medical services) for its employees.

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[333] *Id.* at pg. ii.
[334] Implementation of Task Force Recommendations, Sept. 13, 2017, at pg. 6, *supra* note 271.
[335] *Id.* at pg. 6.
[336] The Opioid Epidemic in Philadelphia: Implementation of the Mayor's Task Force Recommendations, at 11 (Dec. 13, 2017) (hereinafter "*Implementation of Task Force Recommendations*, Dec. 13, 2017"), http://dbhids.org/wp-content/uploads/2017/12/OTF_StatusReport_December2017.pdf.

459. The City self-funds its own pharmacy benefits plan, through which it pays prescription drug costs for covered employees. Through this plan, the City pays for opioids prescribed by physicians to covered employees, their family members, and others.

460. The City pays significant sums for the costs of visits to doctors' offices when covered employees and their family members visit doctors to obtain opioid prescriptions. Many such individuals visit their doctors on a recurring basis due to the long-term nature of opioid treatments.

461. The City pays significant costs for opioid addiction treatment for covered employees and their family members. These costs include, *e.g.*, addiction counseling, rehabilitation costs (inpatient and outpatient), overdose costs (ambulance and emergency room visits), and costs to treat infants born with NAS.

462. The City also pays for medical care needed to treat opioid side effects such as opioid-induced constipation, and other health effects such as hepatitis C virus (HCV) and heart valve infections.

463. National data establish that medical costs incurred by insurers increase by an average of approximately $15,000 per annum for individuals who suffer from opioid abuse or addiction.[337] The City incurs no less than this amount for medical costs per year for each affected employee or family member abusing or addicted to opioids that it insures.

464. Similarly, the City self-funds its own workers' compensation and disability plan, through which it pays disability costs and related benefits for covered employees. Coverage includes payments for wages while absent from work, and medical costs including doctor's visits

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[337] Noam Kirson *et al.*, The Economic Burden of Opioid Abuse: Updated Findings, Journal of Managed Care & Specialty Pharmacy, at pg. 437 (April 2017) ("Opioid abusers generate an average of $14,810 in excess costs to payers in the 6 months before and after the initial abuse episode."), *available at* http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.

and prescription opioid purchases, among other things.

465. Many City employees have been prescribed opioids in connection with injuries sustained at work. Those employees often remain out of work for extended periods of time due to prolonged opioid dependence. The National Council on Compensation Insurance has noted there is "ample evidence that long-term opioid use leads to longer [worker's compensation] claim duration, long-term disability, higher costs, and higher medical expenses."[338] In light of the addictive nature of opioids, the City has incurred costs for workers' compensation claims for longer periods than it otherwise would absent Defendants' conduct in creating the opioid epidemic.

466. The City has experienced lost productivity as a result of employees' work absences due to opioid abuse and addiction, and lost productivity in workers who do show up for work but are impaired by opioid use or withdrawal.

VIII. Increased Costs to Other Affected Persons in Interest in the City from the Opioid Epidemic

467. Residents and other affected persons in interest in or doing business in the City paid considerable sums for opioid prescriptions and incurred significant health care and other costs related to opioids during the period of Defendants' false and deceptive marketing of the drugs.

468. Defendants derived considerable revenue from these affected persons in interest during the period of Defendants' false and deceptive marketing of opioids.

469. Defendants are liable by way of restoration and/or restitution for these costs and revenues.

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[338] NCCI Issues Report: Worker's Compensation 2012, at pg. 24, http://www.akleg.gov/basis/get_documents.asp?session=29&docid=2112.

COUNT I
VIOLATION OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, 73 P.S. §§ 201-1 – 201-9.3 (AGAINST ALL DEFENDANTS)

470. The Commonwealth incorporates by reference all paragraphs set forth above as if fully set forth herein at length.

471. This Count does not sound in fraud.

472. The UTPCPL prohibits persons from employing "[u]nfair methods of competition" and "unfair or deceptive acts or practices," which are defined to include, *inter alia*, the following conduct:

a. "Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services." 73 P.S. § 201-2(4)(ii);

b. "Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have . . . ." 73 P.S. § 201-2 (4)(v); or

c. "Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." 73 P.S. § 201-2 (4)(xxi).

473. Defendants are persons under the UTPCPL.

474. Defendants violated the UTPCPL in that their conduct as alleged herein caused a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of the drugs at issue.

475. Defendants violated the UTPCPL in that by their conduct as alleged herein they represented that the drugs at issue had sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have.

476. Defendants violated the UTPCPL in that by their conduct as alleged herein Defendants engaged in any other fraudulent or deceptive conduct which creates a likelihood of

confusion or of misunderstanding.

477. Under Pennsylvania law, an act or practice is unfair or deceptive if it had the capacity to deceive, or was likely to deceive, a substantial portion of the public, and was likely to make a difference in the purchasing decision.

478. Defendants' conduct as alleged herein constitutes unfair or deceptive acts or practices in violation of the above provisions of the UTPCPL in that:

a. At all relevant times, the Manufacturer Defendants directly, or indirectly through their Third-Party Allies, made and disseminated, or caused to be made and disseminated, materially false and misleading statements directed at the Manufacturer Defendants' target audiences in the Philadelphia area, which included physicians, consumers and PBMs responsible for selecting the drugs covered by the City's health coverage plans and included on the City's pharmacy formularies;

b. These false and misleading statements by the Manufacturer Defendants directly, or indirectly through their Third-Party Allies, were specifically intended to promote the sale and use of opioids to treat chronic pain to members of their target audiences in the Philadelphia area;

c. At all relevant times, the Manufacturer Defendants directly, or indirectly through their Third-Party Allies, made statements that omitted material facts to promote the sale and use of opioids to treat chronic pain;

d. The Manufacturer Defendants directly, or indirectly through their Third-Party Allies, repeatedly failed to disclose or minimized material facts about the risks of opioids, including the life-threatening risks of abuse, misuse, and addiction, and their risks compared to alternative treatments. These omissions were directed at and affected all the target audiences in the Philadelphia area;

e. Such material omissions by the Manufacturer Defendants directly, or indirectly through their Third-Party Allies, were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opioids misleading, creating a false impression of the risks, benefits, and superiority of opioids for treatment of chronic pain;

f. At all relevant times, the Manufacturer Defendants, directly or indirectly through their Third-Party Allies, made and disseminated the foregoing misleading and deceptive statements and omissions through an array of marketing channels including, but not limited to: in-person and other forms of detailing; speaker events, including meals, conferences, and teleconferences; CMEs; journal articles and studies; advertisements; and brochures and other patient education materials;

g. These materially false and misleading statements and omissions by the Manufacturer Defendants directly, or indirectly through their Third-Party Allies, were widely disseminated to the medical community and the public in the Philadelphia area, including the target audiences alleged above;

h. The Manufacturer Defendants knew or should have known that their marketing and promotional efforts created a misleading impression of the risks, benefits and purported superiority of opioids;

i. Defendants, including the Distributor Defendants, intentionally misrepresented their compliance with their affirmative legal obligations to identify and report suspicious orders of prescription opioids, and prevent the shipping and sale of suspicious orders of prescription opioids to retailers and health care providers;

j. The Distributor Defendants knew or should have known that their deceptive and misleading statements regarding the effectiveness of their monitoring systems in identifying,

blocking, and reporting suspicious orders of prescription opioids created the misleading impression that the Distributor Defendants were providing to law enforcement the names of prescribers they knew or should have known to be facilitating the over-prescription and diversion of opioid drugs, while simultaneously distributing opioid drugs to those same prescribers;

k. Defendants' conduct, including their deceptive representations and concealments of material fact, created a significant likelihood of confusion and/or misunderstanding as to the safety, efficacy, and risks of opioids, including the risks associated with the use of opioids for chronic pain;

l. Defendants' conduct had a tendency to deceive a substantial segment of the target audiences in the Philadelphia area, and their misrepresentations and concealments of material facts were likely to be misinterpreted in a misleading way; and

m. Defendants' acts and practices – taken individually and collectively – were likely to make a difference in the prescribing decisions of doctors; usage and purchasing decisions of patients; the formulary decisions of PBMs; and the payment decisions of end-payors like the City, because their misrepresentations and other wrongful acts were specifically designed to mislead and convince these individuals and groups that opioids were safe and superior to alternative treatments for chronic pain.

479. As a direct result of their foregoing acts and practices in violation of the UTPCPL, Defendants have received, and will continue to receive, income, profits, and other benefits, which they would not have received if they had not engaged in violations of the UTPCPL as alleged herein.

480. As a direct result of Defendants' foregoing acts and practices in violation of the UTPCPL, the City and its affected residents and other persons in interest have suffered

substantial injury as alleged herein.

481. As direct result of their foregoing acts and practices in violation of the UTPCPL, Defendants have caused the City and its affected residents and other persons in interest to incur and continue to incur enormous costs and expenses related to the purchase of opioids and the consequences of dealing with the opioid epidemic.

482. As Defendants' foregoing acts and practices in violation of the UTPCPL were a substantial factor in the creation of the opioid epidemic in Philadelphia, as alleged herein, Defendants are responsible for restoring to the City and its affected residents and other persons in interest the enormous costs and expenses which the City and such affected persons in interest have incurred and will incur in responding to the epidemic and otherwise redressing the injuries they have suffered.

483. The Commonwealth seeks all legal and equitable relief as allowed by law, including, *inter alia,* injunctive relief for Defendants' violations of the UTPCPL, as authorized under § 73-201-4. Specifically, the Commonwealth seeks an injunction requiring Defendants to cease all false or misleading promotional, marketing, and advertising activities regarding the use of prescription opioids for chronic pain, and to inform the medical community and the public of the true risks of daily, long-term opioid use.

484. The Commonwealth has reason to believe, based on the facts alleged herein, that the Defendants' omissions, misrepresentations, and practices related to the marketing, advertisement, promotion, and sale of opioids for the treatment of chronic pain have violated, and will continue to violate, the UTPCPL, absent the grant of an injunction.

485. Unless restrained by this Court, the Defendants will likely continue to engage in the methods, acts, or practices which have a likelihood to deceive, mislead and confuse the

public with respect to the use of opioids for chronic pain, all in violation of the UTPCPL.

486. These ongoing, and likely future violations by Defendants of the UTPCPL are contrary to the public interest, thereby necessitating an injunction to restrain and prevent further such misconduct by the Defendants.

487. Pursuant to Section 4 of the UTPCPL, 73 P.S. § 201-4, and due to their respective violations of the UTPCPL set out in this Amended Complaint, the Defendants should further be ordered and directed by the Court to restore to the City and other persons in interest in or doing business in the City, including any health plans or third-party payors administering prescription drug benefits who paid opioid-related claims, any moneys or property, real or personal, which may have been acquired by Defendants by means of their violations of the UTPCPL, including the costs of the opioids themselves, and which the City and other persons in interest in or doing business in the City have been caused to expend or will be required to expend so as to treat, address or otherwise remediate the negative consequences of dealing with opioid addiction and other economic and public health consequences.

488. The Commonwealth also seeks restoration and/or restitution to the City for the costs of increased City services directly associated with opioid addiction, fatal and non-fatal overdoses and other adverse health and public safety conditions, including the increased emergency response costs, hospitalization, and other costs attributable to the Defendants' violations of the UTPCPL.

489. The Commonwealth further seeks and by way of restoration and/or restitution an order directing Defendants to disgorge all monies acquired or retained by Defendants as a result of their violations of the UTPCPL in the City and their violations outside the City which impacted the City and other persons in interest in or doing business in the City.

490. Section 8 of the UTPCPL, 73 P.S. § 201-8, also empowers the Court to impose a civil penalty not exceeding $1,000 for each willful violation of the statute and a penalty not exceeding $3,000 for each violation where the victim is sixty years of age or older.

491. The Commonwealth is entitled to the Court's assessment against Defendants of an appropriate civil penalty for each violation of the UTPCPL by them.

492. The monies demanded herein are in excess of $50,000, exclusive of interests and costs.

WHEREFORE, the District Attorney, in the name of the Commonwealth, respectfully requests that the Court award the following relief against Defendants, jointly and severally, as follows:

a. Enter an order enjoining Defendants from continuing to violate the UTPCPL now and in the future through their deceptive marketing, and directing that Defendants take affirmative steps to provide accurate information the public as to the nature and consequences of opioid drugs;

b. Enter an order requiring Defendants to restore to the City and other affected persons in interest in or doing business in the City, including any health plan providers who paid opioid-related claims, any moneys or property, real or personal, which Defendants may have acquired by means of their violations of the UTPCPL, including the costs of the opioids themselves, and which the City has been caused to expend or will be required to expend so as to remediate or otherwise address the negative consequences of dealing with opioid addiction and consequences attributable to Defendants' violations.

c. Enter an order requiring Defendants to restore to the City the costs of increased City services directly associated with opioid addiction, fatal and non-fatal overdoses and other

adverse health and public safety conditions, including the increased emergency response costs, hospitalization, and other costs attributable to the Defendants' practices, as set forth in this Amended Complaint.

d. Enter an order directing Defendants to disgorge all monies acquired or retained by Defendants as a result of their violations in the City and their violations outside the City which impacted the City and other persons in interest in or doing business in the City.

e. Enter an order awarding the Commonwealth civil penalties under 73 P.S. § 201-8 against Defendants in a sum not exceeding $1,000 for each willful violation of the statute and not exceeding $3,000 for each violation where the victim is sixty years of age or older; and

d. Such other and further relief as the Court deems just and proper.

Dated: November 14, 2018

Respectfully submitted,

By: _____

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VERIFICATION

I, Peter Carr, hereby state that I am an Assistant District Attorney and Supervisor of the Civil Litigation Unit of the Philadelphia District Attorney's Office, and that I have authority to make this verification on behalf of the Commonwealth and the Philadelphia District Attorney. The averments in the Complaint are true and correct to the best of my knowledge, information and belief. I understand that false statements made herein are subject to the penalties of 18 Pa. C.S.A. § 4904 relating to unsworn falsification to authorities.

Date: November 13, 2018

Peter Carr