

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

**SHEET METAL WORKERS LOCAL NO. 25
HEALTH & WELFARE FUND**, on behalf of itself and all
others similarly situated,

Plaintiff

v.

**PURDUE PHARMA, LP, PURDUE PHARMA,
INC., THE PURDUE FREDERICK COMPANY,
INC., ABBOTT LABORATORIES, ABBOTT
LABORATORIES, INC., TEVA PHARMACEUTICALS
USA, INC., CEPHALON, INC., JOHNSON & JOHNSON,
JANSSEN PHARMACEUTICALS, INC., ORTHO-
MCNEIL-JANSSEN PHARMACEUTICALS, INC.
n/k/a JANSSEN PHARMACEUTICALS, INC.,
JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN
PHARMACEUTICALS, ENDO HEALTH SOLUTIONS,
INC., ENDO PHARMACEUTICALS, INC., ALLERGAN
PLC, ACTAVIS, PLC, ACTAVIS, INC., ACTAVIS LLC,
ACTAVIS PHARMA, INC., WATSON
PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC., WATSON PHARMA,
INC., MCKESSON CORPORATION, CARDINAL
HEALTH INC., and AMERISOURCE BERGEN
CORPORATION**

Defendants.

CASE NO. _____

CLASS ACTION COMPLAINT

JURY TRIAL

DEMANDED

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I. INTRODUCTION

1. Plaintiff, Sheet Metal Workers Local No. 25 Health & Welfare Fund (“Local 25”) on behalf of itself and all others similarly situated, brings this Class Action Complaint against Defendants. Plaintiff is a health and welfare benefit fund. At all relevant times, Plaintiff has paid and/or provided reimbursement for some or the entire purchase price on behalf of its members for prescription opioids which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants during the Class Period. Plaintiff has sustained injury as a result of Defendants’ illegal and wrongful conduct alleged herein.

2. Opioids include brand-name drugs like OxyContin and Percocet and generics like oxycodone and hydrocodone. They are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous and therefore are regulated by the United States Food and Drug Administration (“FDA”) as controlled substances.

3. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, and marketed opioids for the management of pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

4. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction.¹ Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

¹ Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

5. Defendants knew that, barring exceptional circumstances, opioids are too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer ("chronic pain").

6. Defendants knew that, with prolonged use, the effectiveness of opioids wanes, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.²

7. Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (*i.e.*, not longer than 90 days) in managed settings (*e.g.*, hospitals) where the risk of addiction and other adverse outcomes was significantly minimized.

8. To date, there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.

9. Despite the foregoing knowledge, in order to expand the market for opioids and realize blockbuster profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches.

10. Defendants accomplished that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the late 1990s, became more aggressive in or about 2006, and continues to the present.

11. Defendants accomplished their marketing campaign goal by convincing doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks, and that opioids could be safely used by most patients.

12. Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists,

² See, *e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

13. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S. has nearly quadrupled.³ In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. In that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).⁴ While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.⁵ By 2014, nearly two million Americans either abused or were dependent on opioids.⁶

14. Defendants' campaign has been extremely profitable for them. In 2012 alone, opioids generated \$8 billion in revenue for drug companies.⁷ Of that amount, \$3.1 billion went to Purdue for its OxyContin sales.⁸

15. Defendants' marketing campaign has been extremely harmful to Americans. Overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half a million people died from such overdoses. Seventy-eight Americans die every day from an opioid overdose.⁹

16. In 2012, an estimated 2.1 million people in the United States suffered from

³ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: <http://www.cdc.gov/drugoverdose/epidemic/index.html> (accessed March 31, 2016) (internal footnotes omitted).

⁴ M. Daubresse, et al., Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013).

⁵ L. Manchikanti, et al., Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten- Year Perspective, 13 Pain Physician 401-435 (2010).

⁶ CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids. Available at: <http://www.cdc.gov/drugoverdose/opioids/prescribed.html> (accessed March 31, 2016).

⁷ B. Meier & B. Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).

⁸ K. Eban, *Purdue Pharma's Painful Medicine*, Fortune Magazine (Nov. 9, 2011).

⁹ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

substance use disorders related to prescription opioid pain relievers.¹⁰ Between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.¹¹

17. Opioid addiction and overdose have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a “public health crisis” that has a “profound impact on individuals, families and communities across our country.”¹² Defendants’ marketing campaign has failed to achieve any material health care benefits. Since 1999, there has been no overall change in the amount of pain that Americans report.¹³

18. The National Institutes of Health (“NIH”) not only recognizes the opioid abuse problem, but also identifies Defendants’ “aggressive marketing” as a major cause: “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.*”¹⁴ As shown below, the “drastic increases in the number of prescriptions written and dispensed” and the “greater social acceptability for using medications for different purposes “ are not really independent causative factors but are in fact the direct result of “ the aggressive marketing by pharmaceutical companies.”

19. The rising numbers of persons addicted to opioids have led to significantly

¹⁰ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

¹¹ J. Boscarino et al., Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, 105(10) *Addiction* 1776 (2010); 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).

¹² FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm> (accessed March 31, 2016).

¹³ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

¹⁴ America’s Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed March 31, 2016) (emphasis added).

increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion¹⁵ and the commission of criminal acts to obtain opioids throughout the United States. The Centers for Disease Control and Prevention (CDC) recently estimated that the total “economic burden” of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement.¹⁶ Consequently, public health and safety throughout the United States has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug.

20. From 1990 to 2015 the average consumption of hydrocodone nationwide increased by 300%. In the same period, there was a 500% increase in the number of Emergency Department visits attributed to hydrocodone abuse with 19,221 visits estimated in 2000.¹⁷

21. Deaths from prescription opioids have quadrupled since 1999. From 2000 to 2014 nearly half a million people died from such overdoses. In 2015 over 33,000 Americans died as a result of an opioid overdose,¹⁸ and an estimated 2 million people in the United States suffered from substance use disorders related to prescription opioid pain medicines (including fentanyl), and 591,000 suffered from a heroin use disorder (not mutually exclusive).¹⁹ Prescription opioid misuse is a significant risk factor for heroin use; 80 percent of heroin users first misuse prescription opioids.²⁰

¹⁵ According to the CDC, when prescription medicines are obtained or used illegally, it is called “drug diversion.”

¹⁶ Florence, C. S., Zhou, C., Luo, F. & Xu, L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Medical Care* 54, 901-906, doi:10.1097/MLR.0000000000000625 (2016).

¹⁷ http://www.crchealth.com/addiction/drug-addiction-rehab/drug-addiction-rehab-2/home-2/hydrocodone_addiction/

¹⁸ Rudd, R. A., Seth, P., David, F. & Scholl, L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. *MMWR Morb. Mortal. Wkly. Rep.* 65, 1445-1452, doi:10.15585/mmwr.mm655051e1 (2016).

¹⁹ Substance Abuse and Mental Health Services Administration National Survey on Drug Use and Health 2015 Detailed Tables. (2016).

²⁰ Muhuri, P. K., Gfroerer, J. C. & Davies, M. C. (CBHSQ [Center for Behavioral Health Statistics and Quality]

22. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors. When turned down by one physician, many of these addicts deploy increasingly desperate tactics—including doctor shopping, use of aliases, and criminal means—to satisfy their cravings, cravings which Defendants first fostered then fueled.

23. In 2014, New Jersey had one of the highest rates of emergency room visits due to opioid abuse.²¹ New Jersey has pursued criminal charges against some doctors and imposed sanctions, including suspension and taking away the license to practice. The crackdown on unscrupulous doctors is part of a concerted effort, as New Jersey Attorney General Christopher Porrino notes, in New Jersey to fight the opioid epidemic on multiple fronts – law enforcement, medical and a preventive educational campaign.²²

24. On October 26, 2017, President Trump directed acting Health Secretary Eric Hargan to declare a public health emergency under the Public Health Services Act. Such a declaration directs federal agencies to provide more grant money to combat the opioid epidemic.²³

25. Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost \$10-\$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law abiding, middle-aged person who started on prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

26. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has incurred and continues to incur costs for opioid prescriptions in excess of those

Data Review, 2013).

²¹ http://www.nj.com/politics/index.ssf/2017/06/opioid_crisis_hit_nj_more_than_most_other_states_r.html

²² <http://www.foxnews.com/us/2017/07/03/opioid-crisis-are-very-much-at-war-here-nj-attorney-general-says.html>

²³ <http://www.cnn.com/2017/10/26/politics/donald-trump-opioid-epidemic/index.html>

they would have otherwise incurred, payments for their insureds' treatment for opioid addiction, and payments for emergency hospital visits for their insureds' including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff.

II. THE PARTIES

Plaintiff

27. Plaintiff **SHEET METAL WORKERS LOCAL NO. 25 HEALTH & WELFARE FUND** ("Local 25") is a New Jersey trust that maintains its principal place of business at 440 Barell Avenue, Carlstadt, NJ 07072, and thus, is a citizen of New Jersey, and is involved in the business of providing health benefits for its members. At all relevant times, Plaintiff has paid and/or provided reimbursement for some or the entire purchase price for prescription opioid's during the Class Period. Plaintiff has sustained injury as a result of Defendants' illegal and wrongful conduct alleged herein.

Defendants

28. Defendant, **PURDUE PHARMA, LP ("PPL")**, is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

29. Defendant, **PURDUE PHARMA, INC. ("PPI")**, is a New York corporation with its principal place of business in Stamford, Connecticut.

30. Defendant, **THE PURDUE FREDERICK COMPANY, INC. ("PFC")**, is a New York corporation with its principal place of business in Stamford, Connecticut.

31. **PPL, PPI, and PFC** (collectively, "**PURDUE**") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in this district, including the following:

Table 1. Purdue Opioids

Drug Name	Chemical Name	Schedule ²⁴
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	Byprenorpine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone	Schedule II

32. OxyContin is Purdue's largest-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 analgesic drugs (*i.e.*, painkillers).

33. Defendant, **ABBOTT LABORATORIES** is a domestic BCA organized under the laws of the State of Illinois with its principal place of business in Abbott Park, Illinois. **ABBOTT LABORATORIES, INC.**, is an Illinois corporation with its principal place of business in Abbott Park, Illinois. (Collectively "**ABBOTT**").

34. Abbott was primarily engaged in the promotion and distribution of opioids nationally, and in the State of New Jersey, due to a co-promotional agreement with Defendant Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products as set forth above.

35. Abbott, as part of the co-promotional agreement, helped make OxyContin into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue, the

²⁴ Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

more Abbott generated in sales, the higher the reward. Specifically, Abbott received 25 to 30 percent of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of 6 percent of net sales up through at least 2006.

36. With Abbott's help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

37. In 2007 Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million. At the time, this was one of the largest settlements with a drug company for marketing misconduct.

38. Defendant, **TEVA PHARMACEUTICALS USA, INC. ("TEVA USA")**, is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

39. Defendant, **CEPHALON, INC.**, is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

40. **TEVA USA** and **CEPHALON, INC.** (collectively, "**CEPHALON**") work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids nationally, and in this district, including the following:

Table 2. Cephalon Opioids

Drug Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II

TEVA USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in this district.

41. Defendant, **JOHNSON & JOHNSON ("J&J")** is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

42. Defendant, **JANSSEN PHARMACEUTICALS, INC.** (“**JANSSEN PHARMACEUTICALS**”) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

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

44. Defendant, **ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.** (“**OMP**”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

45. Defendant, **JANSSEN PHARMACEUTICA, INC.** (“**JANSSEN PHARMACEUTICA**”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

46. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock. 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.

47. **J&J, JANSSEN PHARMACEUTICALS, OMP, and JANSSEN PHARMACEUTICA** (collectively, “**JANSSEN**”) are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in this district, including the following:

Table 3. Janssen Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta ²⁵	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

48. Defendant, **ENDO HEALTH SOLUTIONS, INC.** (“**EHS**”), is a Delaware

²⁵ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

corporation with its principal place of business in Malvern, Pennsylvania.

49. Defendant, **ENDO PHARMACEUTICALS, INC.** (“EPI”), is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

50. **EHS** and **EPU** (collectively, “**ENDO**”) manufacture, promote, distribute and sell opioids nationally and in this district, including 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

Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded revenue of \$1.15 billion from 2010 to 2013, and it accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

51. Defendant, **WATSON LABORATORIES, INC.** is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Defendant, **ALLERGAN PLC** (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant, **ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.)** is a Delaware corporation with its principal place of business in New Jersey and was formerly known as **WATSON PHARMA, INC.** Defendant, **ACTAVIS, LLC** is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Defendant, **ALLERGAN PLC**, which uses them to market and sell its drugs in the United States. Upon information and belief, Defendant, **ALLERGAN PLC** exercises control over these marketing

and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit.

52. **ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., WATSON PHARMACEUTICALS INC., WATSON PHARMA INC., and WATSON LABORATORIES, INC.** are collectively referred to as “**ACTAVIS**”. Actavis manufactures, promotes, sells and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana throughout the United States, including New Jersey, and in this district. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

Distributor Defendants

53. Defendant, **MCKESSON CORPORATION** (“**MCKESSON**”) is a Delaware corporation with its principal place of business in San Francisco, California.

54. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 billion dollars.

55. In its 2017 Annual Report, McKesson states that it “partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.”²⁶

56. According to the 2017 Annual Report, McKesson “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”²⁷

²⁶ McKesson 2017 Annual Report found at investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017_McKesson_Annual_Report_0.pdf

²⁷ *Id.*

57. McKesson is the largest pharmaceutical distributor in the United States.

58. McKesson does substantial pharmaceutical business in New Jersey and has more than 40,000 customers nationally.

59. Defendant, **CARDINAL HEALTH INC.** (“**CARDINAL**”) is an Ohio corporation with its principal place of business in Dublin, Ohio.

60. In 2016, Cardinal generated revenues of \$121.5 billion.

61. Cardinal does substantial pharmaceutical business in New Jersey.

62. Defendant, **AMERISOURCE BERGEN CORPORATION** (“**AMERISOURCE**”) is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

63. According to its 2016 Annual Report, Amerisource is “one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care.”²⁸

64. Amerisource does substantial pharmaceutical business in New Jersey.

65. Defendants McKesson, Cardinal and Amerisource (collectively “Distributor Defendants”) are the three largest opioid distributors in the United States and the State of New Jersey.

66. The Distributor Defendants purchased opioids from manufacturers, such as the Pharmaceutical Defendants, and sold them to pharmacies, which in turn sold them and were paid by Plaintiff and the Class.

67. The Distributor Defendants played an integral role in distributing opioids to employees and/or members of Plaintiff and the Class.

68. The Distributor Defendants owe a duty under federal law (21 USCA §823, 21

²⁸ Amerisource 2016 Annual Report found at <http://www.amerisourcebergen.com/investor/phoenix.zhtml?c=61181&p=irol-irhome>

CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids.

69. The Distributor Defendants were each on notice that the controlled substances they distributed were susceptible to abuse and overuse and were not effective for long-term use.

70. The Distributor Defendants were each on notice that there was an alarming and suspicious increase in opioid distribution to retailers within the State of New Jersey.

71. As entities involved in the distribution of opioid medications, Distributor Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under New Jersey and federal law.

72. The Distributor Defendants had a duty to monitor suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies, including the Drug Enforcement Agency (DEA).

73. The Distributor Defendants failed in their duty to take action to prevent or reduce the distribution of these drugs.

74. The Distributor Defendants were in a unique position and had a duty to monitor, report, or otherwise limit the flow of these drugs throughout the State of New Jersey.

75. The Distributor Defendants were warned in 2006 and 2007 by the DEA about their responsibility to avoid filling suspicious orders.

76. The Distributor Defendants, in the interest of their own massive profits, intentionally failed in this duty.

77. The DEA has repeatedly taken administrative action to force compliance:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;

- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR §1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California; and Denver, Colorado;
- h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA, as well as failure to identify and report suspicious orders at its facilities in Aurora, CO, Aurora, IL, Delran, NJ, LaCrosse, WI, Lakeland, FL, Landover, MD, LaVista, NE, Livonia, MI, Metheun, MA, Santa Fe Springs, CA, Washington Courthouse, OH, and West Sacramento, CA.

78. The Distributor Defendants are members of the Healthcare Distribution Management Association (“HDMA”). The HDMA created “Industry Compliance Guidelines”, which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that “[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers.”

79. The extraordinary increase in the volume of opioid pain medications distributed to New Jersey retailers should have put the Distributor Defendants on notice to investigate and report such orders.

80. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers in the State of New Jersey, which was a proximate cause of Plaintiff and the Class paying for inappropriate opioid prescriptions.

81. The Distributor Defendants knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of the State of New Jersey, including to employees and/or members of Plaintiff and the Class.

82. The Distributor Defendants paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications.

83. The Distributor Defendants made substantial profits from the opioids paid for by Plaintiff and the Class.

84. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of the employees and/or members of the Plaintiff and the Class.

III. JURISDICTION AND VENUE

85. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs, and is a class action in which "any member of a class of Plaintiffs is a citizen of a

state different from any defendant."

86. This Court has further jurisdiction over this action pursuant to the Class Action Fairness Act, because at least one member of the Class is a citizen of a different state than the Defendants and the aggregate amount in controversy exceeds \$5,000,000.00, exclusive of interest.

87. Venue is proper in this District under 28 U.S.C. §1391 because Defendants engaged in substantial conduct relevant to Plaintiff's claims within this District, and have caused harm to Plaintiff and Class members within this District. Defendants received substantial compensation from the sales of their opioid drugs in this District, and Defendants made misrepresentations and material omissions about opioid drugs in this District. Venue is also proper pursuant to 28 U.S.C. §1391(b) because at least one defendant has its principal place of business in this district.

IV. FACTS RELEVANT TO ALL CAUSES OF ACTION

A. The Pain-Relieving and Addictive Properties of Opioids

88. The pain-relieving properties of opium have been recognized for millennia. So has the magnitude of its potential for abuse and addiction. Opioids are related to illegal drugs like opium and heroin.

89. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield – and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States,²⁹ and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive

²⁹ Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

nature.

90. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration (“DEA”) since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and “[s]erious, life-threatening, or fatal respiratory depression,” as the result of an excessive dose.

91. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids’ mixed record in reducing pain long-term and failure to improve patients’ function; greater pain complaints as most patients developed tolerance to opioids; opioid patients’ diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

92. To take advantage of the lucrative market for chronic pain patients, each defendant developed a well-funded marketing scheme based on deception. Each defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long term opioid use. Such statements benefitted not only themselves and the third-parties who gained legitimacy when Defendants repeated those statements, but also other Defendants and opioid manufacturers. These statements were not only unsupported by, or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

93. Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and third-party payors nationwide and in this district. These

promotional messages were intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

94. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million-dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Accordingly, Defendants did not disclose to prescribers, patients, TPP's, or the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Rather, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, doctors nationwide and in this district began prescribing opioids long-term to treat chronic pain – something that most never would have considered prior to Defendants' campaign.

95. Drug company marketing materially impacts doctors' prescribing behavior.³⁰ Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs and payors' willingness to pay for those drugs.

96. Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug

³⁰ See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.³¹ These results are directly due to Defendants' fraudulent marketing campaign.

97. As described in detail below, Defendants:

- misrepresented the truth about how opioids lead to addiction;
- misrepresented that opioids improve function;
- misrepresented that addiction risk can be managed;
- misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- falsely claimed that withdrawal is simply managed;
- misrepresented that increased doses pose no significant additional risks;
- falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

98. Defendants' misrepresentations were aimed at doctors, patients, and third-party payors.

99. Underlying each of Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants' collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.³²

³¹ Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

³² Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

B. Defendants Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids.

100. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the country and in this district. Defendants deployed throughout the state seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain.

101. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each defendant conducted and continue to conduct advertising campaigns touting the purported benefit of their branded drugs. For example, Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The amount included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

102. A number of Defendants' branded ads deceptively portrayed the benefits of Opioids for chronic pain. For example, Endo distributed and made available on its website opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arkansas.

103. Second, each Defendant promoted the use of Opioids for chronic pain through "detailers"- sales representatives who visited individual doctors and medical staff in their offices and small group speaker programs. Defendants have not corrected this misinformation. Instead, each Defendant has devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded Opioids to

doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon on, \$10 million by Endo, and \$2 million by Actavis.

104. Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its 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 Opioids" and, specifically, the risk that "Opioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

1. Defendants Trivialized the Risks of Long Term and Higher Dosages Opioid Therapy.

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

106. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are “frighteningly high.”³³ At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

³³ M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

107. Opioids vary by duration. Long-acting opioids, such as Purdue’s OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon’s Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address “episodic pain” and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

108. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain.

109. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the “grave risks” of opioids, including “addiction, overdose, and even death.” The FDA further warned, “[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death.” Because of those grave risks, the FDA said that long-acting or extended release opioids “should be used only when alternative treatments are inadequate.”³⁴ The FDA required that – going forward – opioid makers of long-acting formulations clearly communicate these risks in their labels.

110. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.³⁵

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013) (emphasis in original).

³⁵ FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm> (accessed March 31, 2016).

111. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants in the 1990s when their deceptive marketing began.

112. Defendants falsely claimed that doctors and patients could increase Opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market Opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients build up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

- a. Actavis' predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options a Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.
- c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was recently available on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased You won't 'run out' of pain relief."
- e. Janssen sponsored a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker 's Guide to Understanding Pain &*

Its Management, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high Opioid dosages. This publication is still available online.

- h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," see www.cpdd.org, challenging the correlation between opioid dosage and overdose.

113. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

114. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

115. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their Opioids has created false impressions that these Opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.³⁶

³⁶ Catherine S. Hwang et al., Prescription Drug Abuse: A National Survey of Primary Care Physicians, 175(2) JAMA Intern. Med. 302-04 (Dec. 8, 2014)

116. More specifically, Defendants have made misleading claims about the ability of their so-called abuse deterrent Opioid formulations to deter abuse. For example, Endo's advertisement for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal, or intravenous abuse." The FDA has subsequently taken the extraordinary action of "request[ing] that Endo Pharmaceuticals remove ... Opana ER ... from the market."³⁷

117. According to the FDA, Endo's reformulation of Opana ER "made things worse": "[P]ostmarketing data ... demonstrate[s] a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation." Moreover, Endo's own studies, which it fails to disclose, showed that Opana ER could still be ground and chewed.

118. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found these statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies - 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."

119. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

120. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers.

³⁷ Maggie Fox, *FDA Asks Drug Company to Pull its Opioid Opana Because of Abuse*, NBCNews.com (June 9, 2017), <http://www.nbcnews.com/story line/americas-heroin-epidemic/fda-asks-drug-company-pull-its-opioid-opana-because-abuse-n770121>

These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to connect Defendants' prior misrepresentations about the risks and benefits of opioids.

121. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Defendants purchase, manipulate, and analyze some of the most sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Defendants *know* their detailing to doctors is effective.

122. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations - which are described below - reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could be easily weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

123. Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples

of these false and deceptive claims are described below:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis' acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."
- d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009), which described as "myth" the claim 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."
- f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* - which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[.]" This publication is still available online.
- h. Detailers for Purdue/Abbott, Endo, Janssen, and Cephalon throughout the country and in the state of New Jersey and in this district omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of Opioids with purportedly abuse deterrent formulations; and routinely did not correct the misrepresentations noted above.

124. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of Opioids (including opioid use disorder

[an alternative term for Opioid addiction])." The Guideline points out that "Opioid pain medication use presents serious risks, including ... opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases the risk for opioid use disorder."

125. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA Opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal Opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," Opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [Opioids]."

126. The warnings on Defendants' own FDA-approved drug labels caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

127. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo had no evidence for that statement.³⁸ Consistent with this, Endo agreed not

³⁸ See *Endo Health Solutions Inc.*, Assurance of Discontinuance, at 6 (N.Y. Att. Gen. Mar. 1, 2016).

to "make statements that ... opioids are generally non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in other states including New Jersey.

128. Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants have called this phenomenon "pseudoaddiction"- a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue - and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

- a. Cephalon and Purdue sponsored *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, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition, which also remains available online, continues to falsely teach that pseudoaddiction is real.
- b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "[P]seudoaddiction ... refers to patient behaviors that may occur when pain is undertreated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of "[drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-

dose, long-acting opioid.

129. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize the risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

130. Defendants employed the same marketing plans and strategies and deployed the same message in New Jersey as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels - including detailing visits, speaker events, and advertising - and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

131. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to check on both their performance and compliance.

2. Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of Opioids.

132. Defendants also deceptively marketed opioids through unbranded advertising - *i.e.*, advertising that promotes opioid use generally but does not name a specific Opioid. This advertising was ostensibly created and disseminated by independent third parties. But by

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

133. Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superiority of opioids to treat chronic pain. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated nationwide, including prescribers and patients in this district.

134. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
“People who take opioids as prescribed usually do not become addicted.”	“All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use.”

a. Key Opinion Leaders ("KOLs")

135. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

136. Defendants paid KOLs to serve as consultants on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

137. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants have created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

138. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were

able to direct and exercise control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

139. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants knew that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.³⁹

140. Thus, even though some of the KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, these admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the State of New Jersey in Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

141. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

(1) Russell Portenoy

142. 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 Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and the Purdue/Abbott cabal.

143. In 1986, Dr. Russell Portenoy published an article reporting that "[f]ew

³⁹ See *In re Purdue Pharma L.P.*, Assurance of Discontinuance, 18, at 8 (N.Y. Att. Gen. Aug. 19, 2015) ("[T]he 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.").

substantial gains in employment or social function could be attributed to the institution of opioid therapy.”⁴⁰

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

*The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*⁴¹

According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”⁴²

145. For all the reasons outlined by Dr. Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year, “it did not enter [doctors’] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost

⁴⁰ R. Portenoy & K. Foley, Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases, 25(2) Pain 171 (1986).

⁴¹ R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

⁴² *Id.*

never saw them.”⁴³

146. Despite his writings in 1994, Dr. Portenoy was instrumental in opening the door for regular use of Opioids to treat chronic pain. He served on the American Pain Society ("APS") American Academy of Pain Medicine ("AAPM") Guideline Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

147. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in New Jersey and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."⁴⁴

148. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." 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 promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of Opioids does not exist."⁴⁵ Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well,

⁴³ J. Loeser. Five crises in pain management, *Pain Clinical Updates*. 2012;20 (1):1–4(cited by I. Kissin, Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?, 6 *J. Pain Research* 513, 514 (2013)).

⁴⁴ *Good Morning America Television Broadcast*, ABC News (Aug. 30, 2010).

⁴⁵ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, *Wall St. J.*, Dec. 17, 2012.

... I guess I did."⁴⁶

(2) Lynn Webster

149. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was president in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

150. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

151. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

152. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patients' 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

⁴⁶ *Id.*

prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors across the country including in New Jersey.

153. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should not be seen as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."⁴⁷

b. Front Groups

154. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

155. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members, whether patients suffering from pain or doctors treating those patients.

⁴⁷John Fauber, *Networking Fuels Painkiller Boom*, Bangor Daily News.

156. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

(1) American Pain Foundation ("APF")

157. The most prominent of Defendants' Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at \$1.7 million.

158. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes -- including death -- among returning soldiers. APF also engaged in a significant multimedia campaign -- through radio, television, and the internet -- to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach New Jersey consumers, physicians, patients, and TPP's.

159. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue), Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF's board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

160. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received

about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephal on, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

161. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2011, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

162. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund those activities and publications, knowing that drug companies would support projects conceived as a result of those communications.

163. APF assisted in other marketing projects for drug companies. One project funded by another drug company -- *APF Reporter's Guide: Covering Pain and Its Management* (2009) recycled text that was originally created as part of the company's training document.

164. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medication generally, the company representative responded, "I provided an advocacy grant to APF this year - this would be a very good issue on which to use some of that. How does that work?"

165. The close relationship between APF and the drug company highlighted in the previous paragraph was not unique, but mirrors relationships between APF and Defendants. APF's clear lack of independence -- in its finances, management, and mission -- and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

166. Indeed the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(2) American Academy of Pain Medicine ("AAPM")

167. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

168. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event - its annual meeting held in Palm Springs, California, or other resort locations. AAPM described the annual event as an "exclusive venue" for offering education programs 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, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

169. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors

and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids -- 37 out of roughly 40 -- at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are ... small and can be managed."⁴⁸

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

171. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

172. In 1997, AAPM and the American Pain Society jointly issues a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

⁴⁸ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

173. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Caphalon, Endo, and Purdue.

174. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache and Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in nationwide and in New Jersey during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

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

176. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

177. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (including AAPM, APS, and American Society of Pain

Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")); and other like-minded organizations, almost all of which received substantial funding from Defendants.

178. PCF, for example, developed and disseminated “consensus recommendations” for a Risk Evaluation and Mitigation Strategy (“REMS”) for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.⁴⁹ This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Defendants’ marketing efforts. The recommendations claimed that opioids were “essential” to the management of pain, and that the REMS “should acknowledge the importance of opioids in the management of pain and should not introduce new barriers.” Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

C. Opioid Therapy Makes Patients Sicker Without Long Term Benefits

179. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. Defendants are well aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Defendants failed to disclose the lack of evidence to support their use long-term and have failed to disclose the substantial scientific evidence that chronic opioid therapy actually makes patients sicker.

180. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients’ pain and function long-term. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use.

181. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients’ health. For example, a 2006 study-of-studies found that opioids

⁴⁹ The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.⁵⁰

182. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

183. While opioids may work acceptably well for a while, when they are used on a long-term basis, function generally declines, as does general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.⁵¹

184. The foregoing is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

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

⁵⁰ A. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) *Can. Med. Ass'n J.* 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) *J. Am. Med. Ass'n* 940 (2012).

⁵¹ See A. Rubenstein, *Are we making pain patients worse?* *Sonoma Medicine* (Fall 2009).

than patients taking other medications.

D. Defendants' Scheme to Change Prescribed Habits and Public Perception

186. Before Defendants began the marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance.

187. The market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Defendants recognized that if they could sell opioids not just for short-term pain relief but also for long-term chronic pain relief, they could achieve blockbuster levels of sales and their profits. Further, they recognized that if they could cause their customers to become physically addicted to their drugs, they would increase the likelihood that their blockbuster profits would continue indefinitely.

188. Defendants knew that in order to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. Defendants needed, in other words, to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

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

190. Marshalling help from consultants and public relations firms, Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, Defendants instead sought to distort medical and public perception of existing scientific data.

191. As explained more fully herein, Defendants, collectively and individually,

poured vast sums of money into generating articles, continuing medical education courses (“CMEs”), and other “educational” materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new but phony “consensus” supporting the long-term use of opioids.

1. Defendants’ Corruption of Scientific Literature

192. Rather than actually test the safety and efficacy of opioids for long-term use, Defendants led physicians, patients, and health care payors to believe that such tests had already been done. As set forth herein, Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

193. To accomplish their goal, Defendants – sometimes through third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of favorable articles in academic journals.

194. Defendants’ plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in Defendants’ marketing departments and with Defendants’ marketing and public relations consultants.

195. In these materials, Defendants (or their surrogates) often claimed to rely on “data on file” or presented posters, neither of which are subject to peer review. Still, Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that Defendants’ materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.

196. Defendants also made sure that favorable articles were disseminated and cited

widely in the medical literature, even when Defendants knew that the articles distorted the significance or meaning of the underlying study. Most 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. It is also cited in two CME programs sponsored by Endo. 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, reproduced in full below, states that the authors examined their files of hospitalized patients who had received opioids.

**ADDICTION RARE IN PATIENTS
TREATED WITH NARCOTICS**

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER

HERSHEL JICK, M.D.

**Boston Collaborative Drug
Surveillance Program**

Waltham, MA 02154 Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D.

Comprehensive drug surveillance. *JAMA*. 1970; 213-1455-60.

2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

197. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those

patients with opioids would have been limited to acute or end-of-life situations, not chronic pain. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor, indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were, for how long. None of these serious limitations was disclosed when Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

198. Dr. Jick has complained that his letter has been distorted and misused – as indeed it has.

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

200. Defendants' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – was flatly inconsistent with their legal obligations. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

2. Defendants' Misuse of Treatment Guidelines

201. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature

and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

a. Federation of State Medical Boards (FSMB)

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

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

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

205. The publication of Responsible Opioid Prescribing was backed largely by drug manufacturers. In all, 163,131 copies of Responsible Opioid Prescribing were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medication (CME) activity for prescribers of opioid medications."

206. Defendants relied on 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions

were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

b. AAPM/APS Guidelines

207. American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.⁵² 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 Russell Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website.

208. 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 21 panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

209. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated nationwide and in this district during the relevant time period, and were and are available online.

⁵² The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997). Available at <http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf> (asviewed 3/31/2016).

210. Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

c. Guidelines that Did Not Receive Defendants' Support

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

212. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians (“ASIPP”), warned that “[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it.” ASIPP’s Guidelines further advise that “therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.” ASIPP recommends long-acting opioids in high doses only “in specific circumstances with severe intractable pain” and only when coupled with “continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects.”⁵³

213. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the “routine use of opioids in the management of patients with chronic pain,” finding “at least moderate

⁵³ Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

evidence that harms and costs exceed benefits based on limited evidence.”⁵⁴

214. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.⁵⁵

E. Defendants’ Promotion of Their Opioid Drugs Was Also Deceptive

215. While Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Defendants called “detailers” to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and in this district. By establishing close relationships with doctors, Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

216. Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors’ prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States, including doctors in this district.

⁵⁴ *American College of Occupational and Environmental Medicine’s Guidelines for the Chronic Use of Opioids* (2011).

⁵⁵ Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf (accessed March 31, 2016).

F. Defendants Knew That Their Marketing of Chronic Opioid Therapy Was False, Unfounded, and Dangerous and Would Harm Plaintiff.

217. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and third-party payors to pay for their opioids for chronic pain.

218. When they began their deceptive marketing practices, Defendants recklessly disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as reasonably foreseeable harm began to occur, Defendants were well aware that it was occurring. Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

G. Defendants Entered into and Engaged in a Civil Conspiracy

219. Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein, and intended to benefit both independently and jointly from their conspiratorial enterprise.

220. Defendants reached an agreement between themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the

management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

221. This network is interconnected and interrelated, and relied upon Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by Defendants, and Defendants relied upon the materials to intentionally mislead consumers, payors, and medical providers of the appropriate uses, risks and safety of opioids.

222. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Defendants committed overt acts in furtherance of their conspiracy.

V. CLASS ACTION ALLEGATIONS

223. Plaintiff brings this suit as a Class action pursuant to Rule 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of a Class consisting of:

All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit provider, in the United States of America and its territories, who have since October 27, 2013, paid or incurred costs for prescription Opioid drugs manufactured, marketed, sold, or distributed by the Defendants, for purposes other than resale, and who, during the same class period incurred costs for treatment related to the misuse, addiction and/or overdose of opioid drugs. Excluded from the Class are employees of Defendants, including their officers or directors, and the Court to which this case is assigned.

224. The following persons are expressly excluded from the Class: (1) Defendants and their subsidiaries, affiliates, and controlled persons; (2) officers, directors, agents, servants, or employees of Defendants, and the immediate family members of any such person; (3) all persons who make a timely election to be excluded from the proposed Class; (4) governmental entities; and (5) the Court to which this case is assigned and its staff.

225. The proposed Class is sufficiently numerous, as thousands of members of the Class were induced to pay for opioid drugs and treatment due to the misuse, addiction and/or overdose through Defendants' scheme. The Class members are so numerous and dispersed throughout the United States that joinder of all members is impracticable. The Class is composed of thousands of third-party payors, and the disposition of their claims in a Class action will benefit both the parties and the Court. It is estimated that in 2007, at least half a million individuals nationwide received prescriptions for opioid drugs. Defendants sell millions of doses of opioid drugs in the United States every year, and thus the Class is sufficiently numerous to make joinder impracticable, if not outright impossible. The Class members can be identified by, *inter alia*, records maintained by Defendants, pharmacies and PBMs.

226. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class members are:

- a. whether Defendants misrepresented the safety and efficacy of opioid drugs, to the financial detriment of the Class;
- b. whether Defendants engaged in a conspiracy to promote the sales of and suppress adverse information about opioid drugs;
- c. whether Defendants' acts and omissions violate, *inter alia*, the State Unfair Trade Practices and State Consumer Protection Laws;
- d. whether Defendants have made material misrepresentations of fact, or omit to state material facts regarding the addiction risks associated with opioid drugs, which material misrepresentations or omissions operate as a fraud and deceit upon the Class;
- e. whether Plaintiff and the class paid more for opioid drugs than for other efficacious drugs that were available at cheaper prices, and/or paid for more opioid drugs due to addiction, and/or paid for treatment including drug addiction treatment, and emergency medical care including the costs of Naloxone Hydrochloride (Narcan) as a result of the abuse, misuse, addiction and/or overdose of opioid drugs.
- f. whether persons who took opioid drugs are at increased risk of severe and permanent injuries, including addiction and overdose;
- g. whether, in marketing and selling opioid drugs, Defendants failed to

- disclose the dangers and risks to the health of persons ingesting the drug;
- h. whether Defendants failed to warn adequately of the adverse effects of opioid drugs, including addiction and overdose;
 - i. whether Defendants misrepresented in their advertisements, promotional materials and other materials, among other things, the safety, potential side effects, and convenience of opioid drugs;
 - j. whether Defendants knew or should have known that the ingestion of opioid drugs leads to serious adverse health effects;
 - k. whether Defendants adequately tested opioid drugs prior to selling it;
 - l. whether Defendants manufactured, marketed, distributed and sold opioid drugs notwithstanding their knowledge of the drugs' dangerous nature;
 - m. whether Defendants knowingly omitted, suppressed and/or concealed material facts about the unsafe and defective nature of opioid drugs from government regulators, the medical community, TPP's, and/or the consuming public;
 - n. whether the Class has been damaged, and if so, the extent of such damages and/or the nature of the equitable relief, statutory damages, or punitive damages to which the Class is entitled;
 - o. whether Defendants were and are unjustly enriched by its acts and omissions, at the expense of the Class;
 - p. the amount of attorneys' fees, prejudgment interest, and costs of the suit to which the Class is entitled.
 - q. whether Defendants engaged in conduct that violates state and federal statutes in promoting the sales of and suppressing adverse information about opioid drugs; and
 - r. whether Defendants engaged in a conspiracy to promote the sales of and suppress adverse information about opioid drugs in violation of federal and state statutes.

227. Plaintiff's claims are typical of the claims of the members of the Class because Plaintiff and the Class sustained damages arising out of the Defendants' wrongful conduct as detailed herein. Specifically, Plaintiff, having expended substantial sums for the purchase of opioid drugs and treatment for their abuse, asserts claims that are typical of the claims of the entire Class, and will fairly and adequately represent and protect the interest of the Class.

228. Plaintiff will fairly and adequately protect the interests of the Class members

and has retained counsel competent and experienced in class action lawsuits.

229. Plaintiff has no interests antagonistic to or in conflict with those of the Class members and therefore should be adequate as a representative for the Class members.

230. A Class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual members of the Class may in some instances be relatively small, the expense and burden of individual litigation make it impossible for such Class members individually to redress the wrongs done to them. Also, the adjudication of this controversy through a Class action will avoid the possibility of inconsistent and possibly conflicting adjudications of the claims asserted herein. There will be no difficulty in the management of this action as a Class action.

VI. CAUSES OF ACTION

COUNT I
VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT

231. Plaintiff incorporates herein by reference all other paragraphs of this Class Action Complaint as if fully set forth herein at length.

232. This cause of action is brought pursuant to the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §56:8-1, et seq. (“NJCFA”), which states, in relevant part:

[A]ny unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise . . . whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice. . . .

N.J. Stat. Ann. § 56:8-2.

233. Plaintiff and the Class are "persons" as defined by the relevant section of the NJCFA. *See, e.g.*, § 56:8-1 (d) (including "natural persons, partnerships, corporation, company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director,

member, stockholder, associate, trustee...).

234. Opioids are “merchandise” within the meaning of N.J. Stat. Ann. *See* § 56:8-1(c).

235. Defendants were engaged in activity “in connection with the sale or advertisement” of “merchandise” because they manufactured and/or sold and/or distributed Opioids.

236. At all times relevant hereto, Plaintiff purchased Defendants’ Opioids on behalf of the Local 25 members, spouses, dependents, and/or retirees from Defendants for personal, family, or household purposes.

237. At all relevant times, Plaintiff and the Class suffered an "ascertainable loss" in the form of, *inter alia*, paying for costs of Opioid prescriptions in excess of those they would have otherwise incurred, payments for their insureds’ treatment for opioid addiction, and payments for emergency hospital visits for their insureds’ including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose.

238. Defendants have engaged in activity “in connection with the sale or advertisement” of “merchandise.” Among other things, Defendants manufactured, advertised, promoted, sold and distributed Opioids.

239. Defendants' ongoing campaign of misinformation, confusion, misrepresentation, and deception violates the NJCFA in at least the following respects:

a. Defendants' conduct described throughout this Class Action Complaint misrepresented the characteristics, uses, and benefits associated with the prescription, purchase, and/or use of Defendants’ Opioids by impermissibly minimizing the risks associated with utilizing Defendant Opioids (e.g., addiction, serious bodily injury, and/or death) and by greatly overstating the potential benefits (e.g., claims regarding increased functionality);

b. Defendants' conduct, described throughout this Class Action Complaint, misrepresented that Defendants' Opioids are of a particular standard, quality, or grade (i.e., safe for use in the therapeutic fashions described by Defendants) when, in reality, they are of a much different standard, quality, or grade (i.e., gravely dangerous in the context of chronic opioid therapy);

c. Defendants' conduct described throughout this Class Action Complaint misrepresented the availability, efficacy, and risks associated with alternatives to chronic opioid therapy (e.g., physical therapy, NSAIDs);

d. Defendants' conduct described throughout this Class Action Complaint failed to comply with the written guarantees and/or warranties given to Plaintiff, the Local 25 members, spouses, dependents, and/or retirees, or prescribing doctors regarding the efficacy of the Defendants' Opioids and the risks associated with chronic opioid therapy (e.g., marketing materials supported, produced, and/or distributed by Defendants); and

e. Defendants' conduct described throughout this Class Action Complaint created a significant likelihood of confusion and/or misunderstanding regarding both the potential and proper uses of Defendants' Opioids, specifically, and chronic opioid therapy, generally.

240. Overall, Defendants misrepresented, deceived, concealed, omitted, and or failed to inform Plaintiff Local 25, its members, spouses, dependents, and retirees, and the doctors prescribing Defendants' Opioids that the use of Defendants' Opioids was neither safe nor efficacious in the treatment of chronic pain or other long-term medical conditions. Defendants' impermissible behavior is well-described throughout this Class Action Complaint, and includes direct and indirect (i.e., carried out by Defendants' agents, employees, representatives, paid

speakers, servants, and/or KOLs) actions: (a) concealing, deceiving, obfuscating, or otherwise misrepresenting the results of definitive medical studies and persuasive empirical research demonstrating the dangers associated with chronic opioid therapy and Defendants' Opioids; (b) deliberately misrepresenting and/or deceptively describing the efficacy of Defendants' Opioids (in particular, OxyContin) at managing chronic pain and other long-term medical conditions; (c) publishing or causing to be published various materials containing false or deceptive information upon which physicians, Plaintiff, and Local 25's members, spouses, dependents, and retirees relied upon in choosing to prescribe, pay for, or take Defendant Opioids when safer, more effective, and less expensive treatments were available for the management of chronic pain and other long-term medical conditions; and (d) otherwise creating confusion and uncertainty regarding the safe, recommended, and medically sound therapeutic uses of Defendants' Opioids.

241. By reason of the foregoing, Plaintiff and the Class have been harmed and damaged, entitling them, pursuant to the NJCFA to injunctive relief, awarding damages, reasonable attorneys' fees, and other proper relief available under the NJCFA. N.J. Stat. Ann. § 56:8-19.

WHEREFORE, Plaintiff and the Class respectfully request that this Honorable Court enter judgment against Defendants on Count I and award Plaintiff and the Class damages for each instance of unfair or deceptive acts including, but not limited to, each instance in which Defendants misrepresented and/or deceptively represented the efficacy and risks associated with, or otherwise obfuscated the truth regarding the therapeutic uses of Defendant Opioids and chronic opioid therapy, together with reasonable attorneys' fees and other proper relief available under the NJCFA, as the Court deems appropriate.

COUNT II
UNJUST ENRICHMENT /RECISSION /RESTITUTION

242. Plaintiff incorporates herein by reference all other paragraphs of this Class Action Complaint as if fully set forth herein at length.

243. Defendants are the manufacturer, marketer, seller, and/or supplier of Defendant Opioids. Through the wrongful and deceptive conduct described at length above, Defendants have reaped substantial profits from the sale of Defendant Opioids. Yet, Defendants' profits would have been significantly and substantially reduced but for its wrongful, deceptive and unlawful conduct.

244. Accordingly and as described in this Class Action Complaint, Defendants have been unjustly enriched by its unlawful, deceptive and wrongful conduct. Defendants should not be permitted to retain the proceeds from the benefits conferred upon them by Plaintiff and the Class (i.e., the purchase and/or reimbursement for purchase of Defendant Opioids). Defendants knew that Plaintiff and the Class paid for, or reimbursed for purchases of, Defendant Opioids that were not medically necessary, generally ineffective, and fundamentally unsafe. Moreover, the use of Defendant Opioids in the treatment of chronic pain and/or other long-term medical conditions offered no greater benefits than those offered by less expensive medications and treatment options.

245. It is unjust and inequitable to permit Defendants to enrich themselves at the expense of Plaintiff and the Class by retaining the benefit of the various expenditures for Defendant Opioid prescriptions that were not medically necessary, effective, or, alternatively, no more efficacious than less expensive, substantially safer medical alternatives, or that were simply the result of Defendants' own self-created demand due to its own deceptive marketing strategies. Accordingly, Defendants must disgorge their unjustly acquired profits

and other monetary benefits resulting from their unlawful conduct and provide restitution and/ or rescission to Plaintiff and the Class.

WHEREFORE, Plaintiff and the Class respectfully requests that this Honorable Court enter judgment in their favor and against Defendants for compensatory and actual damages related to their purchases and reimbursement for purchases of Defendant Opioids, in amounts to be determined by the Court, together with interest, costs of litigation, attorneys' fees, and any other such relief as this Honorable Court may deem just and proper.

COUNT III
BREACH OF IMPLIED WARRANTIES

246. Plaintiff incorporates herein by reference all other paragraphs of this Class Action Complaint as if fully set forth herein at length.

247. Defendants, in the manufacture, marketing, and sale of Defendant Opioids impliedly warranted to Plaintiff and the Class that Defendant Opioids were appropriate for its particular and understood ordinary purpose as presented by Defendants: namely, the treatment of chronic pain and/or other long-term medical conditions.

248. Defendants and their agents, employees, servants, paid speakers, KOLs and/ or other representatives knew or should have known that the Defendant Opioids were ineffective (and inherently dangerous) treatment options in the management of chronic pain and other long-term medical conditions.

249. Plaintiff and the Class reasonably relied upon the skill and judgment of Defendants and their agents, employees, servants, paid speakers, KOLs and/or other representatives as to whether Defendant Opioids were of merchantable quality, safe, and fit for their intended uses as described by Defendants.

250. Pursuant to the New Jersey's Uniform Commercial Code there exists an implied

warranty of merchantability for Defendants' marketing and sale of Defendant Opioids.

251. Defendants breached this implied warranty of merchantability by promoting, marketing, and selling Defendant Opioids as being fit for the "ordinary purpose" ascribed by Defendants (i.e., the treatment of chronic pain and/or other long-term medical conditions) when, in fact, Defendant Opioids are inappropriate, dangerous, and unfit for that purpose.

WHEREFORE, Plaintiff and the Class respectfully requests that this Honorable Court enter judgment for them and against Defendants, for compensatory and consequential damages related to their purchases and reimbursements for purchases of Defendant Opioids, in amounts to be determined by the Court, together with interest, costs of litigation, attorneys' fees, and all other such relief as this Honorable Court may deem just and proper.

COUNT IV
CIVIL CONSPIRACY

252. Plaintiff incorporates herein by reference all other paragraphs of this Class Action Complaint as if fully set forth herein at length.

253. Defendants conspired with various KOLs and Front Groups, and each other, as described throughout this Class Action Complaint in order to commit unlawful acts, including the serial violations of the New Jersey law detailed at length above. In particular, Defendants and the various KOLs and Front Groups knowingly and voluntarily agreed to engage in unfair, misleading, and deceptive practices in order to promote the use of Defendant Opioids for the treatment of chronic pain and other long-term medical conditions. To that end, Defendants enlisted various KOLs and Front Groups to produce and disseminate statements and materials in furtherance of this common strategy, despite knowledge of the misleading nature of these activities.

254. Together with and in collusion with Front Groups, Defendants agreed to

deceptively and misleadingly promote the benefits and superiority of chronic opioid therapy and Defendant Opioids, while minimizing the associated risks. As part of these agreements, Defendants provided material, financial, and other forms of support to the Front Groups, which in turn used that support to more broadly disseminate the deceptive and misleading messaging regarding Defendant Opioids and chronic opioid therapy. The publications, marketing materials, and substantive representations produced and publicized by these Front Groups are each products of a civil conspiracy, and each instance of collaboration between Defendants and the Front Groups is evidence of an overt act taken in furtherance of that conspiracy.

255. Each of the participants in this conspiracy were fully aware of the deceptive and misleading nature of the statements, research, and other materials that they utilized in promoting Defendant Opioids. Nonetheless, Defendants and the Front Groups agreed to mislead and deceive Plaintiff and the Class regarding the risks, benefits, and alleged superiority of chronic opioid therapy and the Defendant Opioids, in exchange for increased pharmaceutical sales, financial contributions, reputational enhancements, and other pecuniary and professional benefits.

256. As outlined at length above, Defendants played an active role in determining the substance and format of the misleading and deceptive messaging issued by KOLs and Front Groups, including directly providing content, editing, and otherwise approving content produced by their co-conspirators. Defendants, KOLs, and the Front Groups also collectively ensured that these materials were widely disseminated by cooperative distribution, material support and republication. The result was an unrelenting stream of misleading information regarding the risks, benefits, and alleged superiority of chronic opioid therapy and the Defendant Opioids.

257. Even if Defendants did not directly disseminate or control the content of all of these misleading and deceptive representations, they are liable for conspiring with the third parties that did so (i.e., KOLs and Front Groups).

258. Defendants' conspiracy, and the consummation of that conspiracy via the overt acts described above, with these third parties were unlawful acts under New Jersey law.

259. As a result of Defendants' conspiracy and related unlawful acts, Plaintiff and the Class have been damaged and continue to be damaged by paying for the costs of or reimbursements for Defendant Opioids for the treatment of chronic pain and/or other long-term medical conditions.

260. Because Defendants' conspiracy ultimately caused doctors and other health care providers to prescribe (and, consequently, Plaintiff and the Class to pay for) long-term treatments via Defendant Opioids, Defendants caused and is responsible for those costs and claims.

WHEREFORE, Plaintiff and the Class respectfully requests that this Honorable Court enter judgment for them and against Defendants, for direct and consequential damages related to their purchases and reimbursements for purchases of Defendant Opioids, in amounts to be determined by the Court, together with interest, costs of litigation, attorneys' fees, and all other such relief as this Honorable Court may deem just and proper.

COUNT V
NEGLIGENCE - Against Distributor Defendants

261. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs.

262. Distributor Defendants have a duty to exercise reasonable care in the distribution of opioids.

263. Distributor Defendants breached their duty of care by failing to monitor and reduce the distribution of opioids.

264. Distributor Defendants placed their profit motives above their legal duty and enabled, encouraged and caused the over-prescribing and distribution of opioids.

265. Distributor Defendants intentionally and/or negligently failed to perform their duty to help to prevent the over-prescription of opioids.

266. The Plaintiff and the Class are without fault and they would not have paid millions of dollars in inappropriate prescriptions but for the wrongful conduct of the Distributor Defendants.

267. The Distributor Defendants were a proximate cause of the over-prescription of the opioids and, hence, the millions of dollars in inappropriate prescriptions paid for by Plaintiff and the members of the putative Class.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands Judgment for the following relief:

1. The Court determine that this action may be maintained as a class action under Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable Notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Civil Procedure, be given to each and every member of the Class;
2. Plaintiff and members of the Class be awarded compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff and the Class for all damages; punitive damages as provided by law; pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate;
3. Plaintiff and members of the Class recover their costs of suit, including

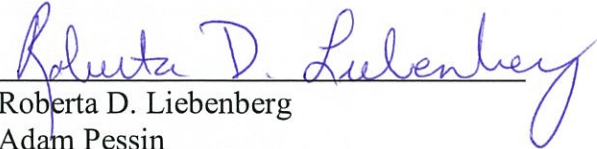
reasonable attorneys' fees, as provided by law; and

4. Plaintiff and members of the Class have such other and further relief as the case may require and the Court may deem just and proper.

November 9, 2017

Respectfully submitted:

FINE, KAPLAN AND BLACK, R.P.C.



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*Attorneys for Sheet Metal Workers Local 25 New
Jersey Health & Welfare Fund, and the Proposed
Class.*

CIVIL COVER SHEET

17-CV-5079

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Sheet Metal Workers Local No. 25 Health & Welfare Fund

(b) County of Residence of First Listed Plaintiff Bergen County, NJ (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

SEE ATTCHMENT A

DEFENDANTS

SEE ATTACHMENT B

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country
1 Incorporated or Principal Place of Business In This State
2 Incorporated and Principal Place of Business In Another State
3 Foreign Nation
4
5
6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories and checkboxes.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District (specify)
6 Multidistrict Litigation - Transfer
8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 18 U.S.C. § 1961, et seq.

Brief description of cause: Conspiracy arising from the fraudulent and deceptive marketing and sale of opioid drugs

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Timothy J. Savage DOCKET NUMBER 17-cv-04746

DATE 11/9/17 FOR OFFICE USE ONLY

SIGNATURE OF ATTORNEY OF RECORD: Roberta D. Lubenberg

ATTACHMENT A
PLAINTIFFS' COUNSEL

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Adam J. Pessin
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ATTACHMENT B

DEFENDANTS

PURDUE PHARMA, LP
201 Tresser Blvd.
Stamford, CT 06901

PURDUE PHARMA, INC.
201 Tresser Blvd.
Stamford, CT 06901

THE PURDUE FREDERICK COMPANY, INC.
201 Tresser Blvd.
Stamford, CT 06901

ABBOTT LABORATORIES
100 Abbott Park Road
Abbott Park, IL 60064

ABBOTT LABORATORIES, INC.
100 Abbott Park Road
Abbott Park, IL 60064

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

CEPHALON, INC.
41 Moores Road
Frazer, PA 19355

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

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

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.
n/k/a JANSSEN PHARMACEUTICALS, INC.
1125 Trenton-Harbourton Road
Titusville, NJ 08560

JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS
1125 Trenton-Harbourton Road
Titusville, NJ 08560

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

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

ALLERGAN PLC
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS INC.
311 Bonnie Circle
Corona, CA 92880

WATSON LABORATORIES, INC.
311 Bonnie Circle
Corona, CA 92880

ACTAVIS, LLC
400 Interpace Parkway
Parsippany, NJ 07054

ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.
400 Interpace Parkway
Parsippany, NJ 07054

MCKESSON CORPORATION
One Post Street
San Francisco, CA 94104

CARDINAL HEALTH INC.

7000 Cardinal Place

Dublin, Ohio 43017

AMERISOURCE BERGEN CORPORATION

1300 Morris Drive

Chesterbrook, PA 19087

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 440 Barell Avenue, Carlstadt, NJ

Address of Defendant: See attached

Place of Accident, Incident or Transaction: United States

(Use Reverse Side For Additional Space)

publicly held corporation owning 10% or more of its stock?

Yes No

Yes No

terminated:

previously terminated action in this court?

Yes No

pending or within one year previously terminated

Yes No

and case pending or within one year previously

Yes No

initiated by the same individual?

Yes No

THIS CASE IS RELATED TO: 17-CV-4746

CIVIL ACTION NO.
CRIMINAL NO.

ASSIGNED TO: TJS

CIVIL: (Place in ONE CATEGORY ONLY)

A. Federal Question Cases:

- 1. Indemnity Contract, Marine Contract, and All Other Contracts
- 2. FELA
- 3. Jones Act-Personal Injury
- 4. Antitrust
- 5. Patent
- 6. Labor-Management Relations
- 7. Civil Rights
- 8. Habeas Corpus
- 9. Securities Act(s) Cases
- 10. Social Security Review Cases
- 11. All other Federal Question Cases
(Please specify) _____

B. Diversity Jurisdiction Cases:

- 1. Insurance Contract and Other Contracts
- 2. Airplane Personal Injury
- 3. Assault, Defamation
- 4. Marine Personal Injury
- 5. Motor Vehicle Personal Injury
- 6. Other Personal Injury (Please specify)
- 7. Products Liability
- 8. Products Liability — Asbestos
- 9. All other Diversity Cases

(Please specify) State Law / Consumer Protection

ARBITRATION CERTIFICATION

(Check Appropriate Category)

Roberta D. Liebenberg

counsel of record do hereby certify:

Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;
 Relief other than monetary damages is sought.

DATE: 11/9/17

Roberta D. Liebenberg
Attorney-at-Law

31738
Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 11/9/17

Roberta D. Liebenberg
Attorney-at-Law

31738
Attorney I.D.#

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Sheet Metal Workers Local No. 25 Health &
Welfare Fund

v.

Purdue Pharma, LP, et al.

:
:
:
:
:
:

CIVIL ACTION

79

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ()
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ()

<u>11/9/17</u>	<u>Robert D. Liebenberg</u>	Plaintiff
Date	Attorney-at-law	Attorney for
<u>215-567-6565</u>	<u>215-568-5872</u>	<u>rliebenberg@finekaplan.com</u>
Telephone	FAX Number	E-Mail Address

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Lawsuit: Pharma Companies and Distributors Contributed to Opioid Crisis](#)
