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COUNTY OF LACKAWANNA, Plaintiff, vs. PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, 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, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC F/K/A ACTAVIS PLC; ACTAVIS, INC. F/K/A WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; RUSSEL PORTENOY; PERRY FINE; SCOTT FISHMAN; and LYNN WEBSTER, Defendants.	:	COURT OF COMMON PLEAS LACKAWANNA COUNTY, PA CIVIL ACTION – LAW NO.: 17-CV 5156 JURY TRIAL DEMANDED

MAURI B. KELLY
LACKAWANNA COUNTY
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CLERKS OF JUDICIAL
RECORDS CIVIL DIVISION

COMPLAINT AT LAW

Plaintiff, the County of Lackawanna County, Pennsylvania ("Plaintiff"), by and through the undersigned attorneys, upon personal knowledge as to its own acts and beliefs, and upon information and belief as to all matters based upon the investigation of counsel, for its Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company; 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 f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; (collectively, "Manufacturers" or "Defendants"); McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Corporation; (collectively, "Distributor Defendants" or "Defendants"); Russell Portenoy; Perry Fine; Scott Fishman; and Lynn Webster; (collectively, "Physicians" or "Defendants"); alleges as follows:

INTRODUCTION

1. Plaintiff spends millions of dollars each year to provide or pay for the health care, pharmaceutical care, and other necessary services and programs on behalf of indigents and otherwise eligible residents, including payments for prescription opium-like painkillers ("opioids"), which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.

2. Plaintiff not only provides a wide range of other services on behalf of its residents, including services for families and children, public assistance, and law enforcement, but also depends on the health and productivity of its workforce to generate tax revenue.

3. Opioids include brand-name drugs like OxyContin and Percocet and generics like oxycodone and hydrocodone. These drugs 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.

4. 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.

5. 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.

6. 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").

7. Defendants knew that, with prolonged use, the effectiveness of opioids wane over time, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.[2]

8. Defendants knew that controlled studies of the safety and efficacy of opioids were

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

[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).

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.

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

10. 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.

11. 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.

12. 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.

13. Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

14. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled.[3] In

[3] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: http://www.cdc.gov/drugoverdose/epidemic/index.html (accessed September 19, 2017) (internal footnotes omitted).

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]

15. 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]

16. 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]

17. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.[10] Between 30% and 40% of

[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 September 19, 2017).
[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.*
[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.

long-term users of opioids experience problems with opioid use disorders.[11]

18. Opioid addiction and overdoses 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]

19. 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]

20. 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."

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

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[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 September 19, 2017).

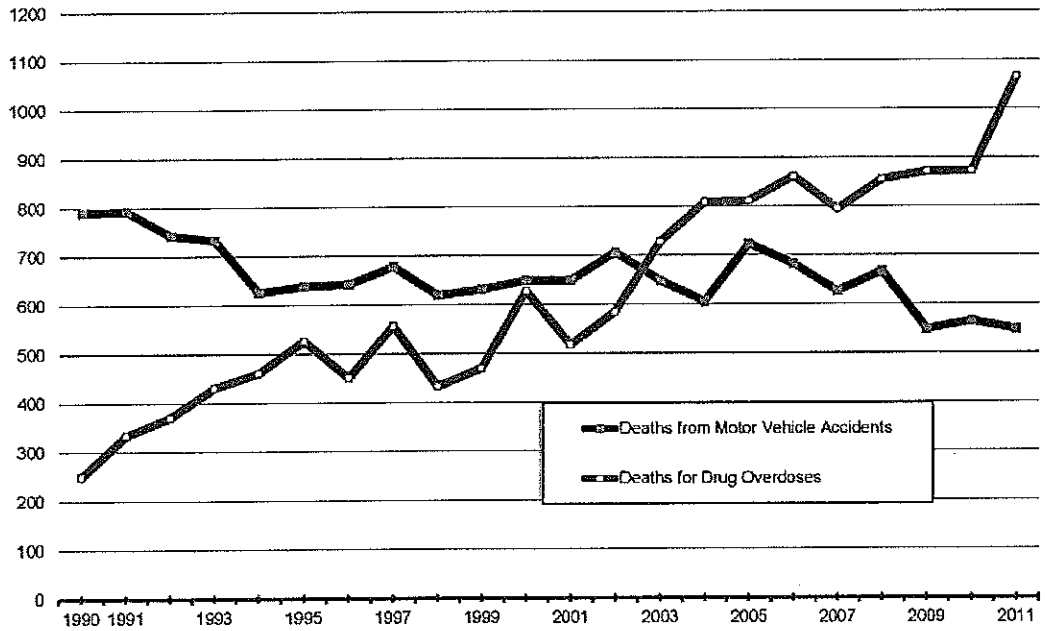
[13] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra.*

[14] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse (accessed September 19, 2017) (emphasis added).

increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion[15] and the commission of criminal acts to obtain opioids throughout the United States, including Pennsylvania and Lackawanna County. Consequently, public health and safety throughout the United States, including Lackawanna County, 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.

22. Opioid abuse is widespread across the Commonwealth of Pennsylvania, affecting one of every four families in the state. Between 2009 and 2011, overdose deaths increased 470% according to data from the Pennsylvania Department of Health. Since 2002, more adults age 20 to 44 have died from drug overdoses than motor vehicle accidents in the state:

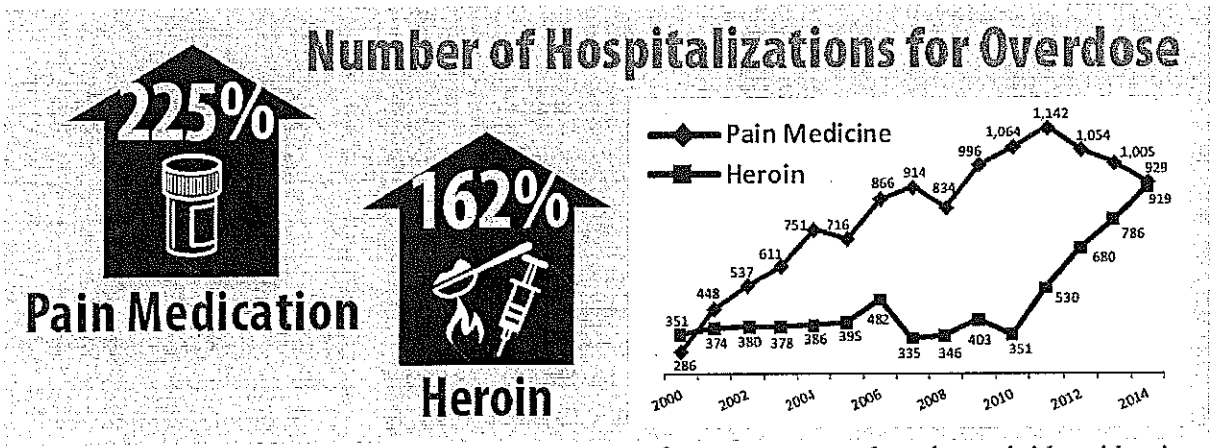
Number of Deaths from Drug Overdoses and Motor Vehicle Accidents among Pennsylvania Adults Age 20 to 44, 1990 to 2011



Additionally, "data from the Pennsylvania Department of Health and the Pennsylvania Department

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

of Drug and Alcohol Programs (DDAP) revealed that approximately 52, 150 Pennsylvania residents receiv[ed] addiction treatment services in the Commonwealth" with 760,703 remaining untreated in 2011.[16] A report published in October 2016 by the Pennsylvania House Majority Public Safety Committee found that the state now leads the nation in drug overdoses among men aged 12 to 25.[17] For the year 2012, opioid overdose related hospitalizations alone required $12.2 Million in state payments, with a 290% total increase in the number of hospitalizations from the year 2000.[18] Tragically, the state spent an estimated $23 million in 2015 for treatment relating to newborn and infant substance-related conditions, with neonatal abstinence syndrome, a condition caused by infant drug withdrawal, accounting for 82% of those hospitalizations.[19]



23. Pennsylvania has spent vast sums of money to combat the opioid epidemic, spending millions of dollars to build infrastructure for detox and long-term residential facilities for

[16] The Center for Rural Pennsylvania, *Heroin: Combating this Growing Epidemic in Pennsylvania 5-6*, http://www.rural.palegislature.us/documents/reports/heroin_report2014.pdf, (September 2014, accessed September 19, 2017).

[17] House Majority Policy Committee, *Combating Pennsylvania's Opioid Epidemic*, http://www.pahouse.com/files/Documents/Testimony/2016-10-26_21-42-30__JointOpioidReport.pdf, (October 2016, accessed September 19, 2017).

[18] Pennsylvania Health Care Cost Containment Counsel, *Hospitalizations for Overdose of Pain Medication and Heroin*, http://www.phc4.org/reports/researchbriefs/overdoses/012616/docs/researchbrief_overdose2000-2014.pdf (accessed September 19, 2017).

[19] Pennsylvania health Care Cost Containment Counsel, *Neonatal and maternal Hospitalizations Related to Substance Use*, http://www.phc4.org/reports/researchbriefs/neonatal/092716/docs/researchbrief_neonatal_2000-2015.pdf (accessed September 19, 2017).

those effected.[20] One report estimated that in 2012, the state spent a total of $874 million on health care costs alone relating to opioid abuse, with all metrics pointing to that number increasing since then.[21] The Commonwealth of Pennsylvania has expended funds to combat the opioid problem with non-treatment programs, as well. For example, the Pennsylvania Drug Take-Back Box Program has successfully collected and destroyed over 300,000 pounds of prescription drugs. The Pennsylvania Department of Drug and Alcohol Programs (DDAP) led the state's efforts to implement "David's Law," which makes the emergency overdose reversal drug Naloxone available to police, firefighters, and family members of those at risk of overdose. "As of August 2016, more than 430 municipal police department across the Commonwealth were equipped with Naloxone through DDAP's efforts."[22] Despite these efforts, costs to the state continue to grow – the Pennsylvania Legislature recently approved a budget for 2017-2018 that will increase state spending for programs specifically designed to address the opioid epidemic these Defendants caused by 19%, totaling nearly $76 million.[23]

24. Pennsylvania's youth have been negatively impacted by prescription opioids, with 24.3% reporting that it would be "sort of easy" or "very easy" to obtain prescription opioids not prescribed to them. The Pennsylvania Youth Survey asked students in 6th, 8th, 10th, and 12th grades about their experience with prescription narcotics. 6.8% of the students surveyed said they had used prescription narcotics not prescribed to them in their lifetime, with 12.1% of 12th graders

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[20] House Majority Policy Committee, *Combating Pennsylvania's Opioid Epidemic*, *Supra.*

[21] Joint State Government Commission, *Opioid Addiction Treatment in Pennsylvania* 20, http://jsg.legis.state.pa.us/resources/documents/ftp/publications/2017-06-27%20MAT%20FINAL%20DRAFT%2006.26.17.pdf (June 27, 2017, accessed September 20, 2017).

[22] Pennsylvania Department of Drug and Alcohol Programs, *Overdose Response*, http://www.ddap.pa.gov/overdose/Pages/Department%20Focus%20on%20Addressing%20Overdose.aspx (accessed September 19, 2017).

[23] Associated Press, *House, Senate Send Pennsylvania budget to Gov. Wolf*, http://www.lehighvalleylive.com/news/index.ssf/2017/06/house_senate_send_pennsylvania.html, (posted June 30, 2017, 5:39pm EDT, accessed September 19, 2017).

reporting use. An alarming number of Pennsylvania youth reportedly believed there was little or no risk in using prescription drugs not prescribed to them.[24]

25. Lackawanna County has been hit particularly hard by the opioid epidemic. 88 painkiller prescriptions exist for every 100 Lackawanna County residents. In Lackawanna County, a person dies from a fatal opioid overdose every 4 days, even though it took on the expense of equipping its police force with lifesaving Naloxone. Between 2014 and 2015, the County saw a nearly 200% increase in overdose deaths. Additionally, crime has increased as well, with the Lackawanna County Drug Task Force arresting 577 people for drug related offenses between January 2016 and March 2017, severely straining the County prison and justice system from the increased criminal activity caused by opioid addiction.[25]

26. On the County level, substance abuse treatment is largely managed by "Single County Authorities." The Single County Authority in Lackawanna County spent $2,788,471 on substance abuse programming in the 2013-2014 State Fiscal Year alone.[26] Sadly, 2% of all babies born in Lackawanna County in 2015 required substance related treatment, with 82% of those being related to drug withdrawal.[27]

27. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants'

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[24] Joint State Government Commission, *Supra.*
[25] Lackawanna County District Attorney's Office, 2017, http://www.heroinhitshome.com/ (accessed September 19, 2017).
[26] Joint State Government Commission, *Supra.*
[27] Pennsylvania Health Care Cost Containment Counsel, *Neonatal and Maternal Hospitalizations Related to Substance Use, Supra.*

misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents.

JURISDICTION AND VENUE

28. This Court has jurisdiction over this action pursuant to Pa. Const. Art. V, §§ 4 and 42 Pa.C.S.A. § 761; 42 Pa.C.S.A. § 931(a); and 42 Pa.C.S.A. § 5322.

29. Venue is proper in Lackawanna County pursuant to 42 Pa.C.S.A. § 931(c) and Pa.R.C.P. No. 2179(a)(4).

30. This action is non-removable because there is incomplete diversity of residents and no substantial federal question is presented.

PARTIES

31. Lackawanna County comprises 50 communities in northeastern Pennsylvania with a population of 214,437 as of the 2010 Census. Plaintiff has a duty to provide a wide range of services to its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care. As mentioned above, Plaintiff also funds its own health insurance plan for its approximately 1,500 employees.

32. Plaintiff brings this action on its own behalf and also as subrogee of its employees and residents and, as such, Plaintiff stands in the shoes of its subrogors, and is entitled to all the rights of its subrogors. In making the payments it has made on behalf of its employees and residents, Plaintiff did not act as a volunteer but rather acted under compulsion, for the protection of its interests, or as *parens patriae*.

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

34. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal

place of business in Stamford, Connecticut.

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

36. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Lackawanna County, including OxyContin (Oxycodone hydrochloride extended release), MS Contin (Morphine sulfate extended release), Dilaudid (Hydromorphone hydrochloride), Dilaudid-HP (Hydromorphone hydrochloride), Butrans (Byrenorpine), Hysingla ER (Hyrdrocodone bitrate), and Targiniq ER (Oxycdone hydrocholoride and Naloxone hydrochloride), all of which except Butrans are Schedule II.[28]

37. 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).

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.

[28] 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. Of the Purdue drugs listed above, Butrans is the only Schedule III drug.

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 Lackawanna County, including Actiq (Fentanyl citrate) and Fentora (Fentanyl citrate tablet), both Schedule II drugs.

41. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in Lackawanna County.

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

43. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with is principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

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

45. 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.

46. 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.

47. 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.

48. 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 Lackawanna County, including Duragesic (Fentanyl), Nucynta (Tapentadol), and Nucynta ER (Tapentadol extended release), all of which are Schedule 2 drugs.[29]

49. 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.

50. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

51. 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.

52. EHS and EPI (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and in Lackawanna County, including Opana ER (Oxymorphone hydrochloride extended release), Opana (Oxymorphone hydrochloride), Percodan (Oxymorphone hydrochloride and aspirin), and Percocet (Oxymorphone hydrochloride and acetaminophen).

53. Opioids make 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.

54. Allergan plc is a public limited liability company incorporated in Ireland with its

[29] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in March 2015. Prior to that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. in January 2013 and then to Actavis plc in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California and is a wholly owned subsidiary of Allergan plc (f/k/an Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. f/k/a Actavis, Inc. is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts; profits from the sale of Allergan/Actavis products; and ultimately benefits from them (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter collectively are referred to as "Actavis.").

55. Actavis manufactures, promotes, distributes, and sells the branded opioids Kadian (morphine sulfate extended release) and Norco nationally and within Lackawanna County. Kadian is a Schedule II drug. Actavis also sells a generic version of Kadian, Duragesic, and Opana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

56. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California.

57. McKesson promotes, distributes, and sells opioids manufactured by Manufacturers

across the country and, upon information and belief, within Pennsylvania and Lackawanna County to pharmacies and institutional providers. It had a net income over $1.5 Billion in 2015.

58. Defendant Cardinal Health Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio.

59. Defendant Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including, on information and belief, Pennsylvania and Lackawanna County.

60. Upon information and belief, Defendant AmerisourceBergen Drug Corporation ("Amerisource") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania.

61. Defendant Amerisource does substantial business as a pharmaceutical distributor to retail pharmacies and institutional providers in the State of Pennsylvania and Lackawanna County.

62. The three pharmaceutical Distributor Defendants, Cardinal, Amerisource, and McKesson are three of the largest opioid distributors in Lackawanna County.

63. Russell Portenoy, M.D., is an individual residing in New York. Dr. Portenoy was instrumental in promoting opioids for sale and distribution nationally and in Lackawanna County.

64. Perry Fine, M.D., is an individual residing in Utah. Dr. Fine was instrumental in promoting opioids for sale and distribution nationally and in Lackawanna County.

65. Scott Fishman, M.D., is an individual residing in California. Dr. Fishman was instrumental in promoting opioids for sale and distribution nationally and in Lackawanna County.

66. Lynn Webster, M.D., is an individual residing in Utah. Dr. Webster was

instrumental in promoting opioids for sale and distribution nationally and in Lackawanna County.

GENERAL FACTUAL ALLEGATIONS

A. THE PAIN-RELIEVING AND ADDICTIVE PROPERTIES OF OPIOIDS

67. The pain-relieving properties of opium have been recognized for millennia. Likewise, the magnitude of opium's potential for abuse and addiction has been well-known for ages and has led to its strict regulation world-wide. Opioids, similar to the illegal drugs opium and heroin, are substances that act on opioid receptors to produce morphine-like effects.

68. 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,[30] 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 nature.

69. 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.

70. 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'

[30] 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).

function; greater pain complaints as most patients developed a 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.

71. In 1986, Dr. Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[31]

72. 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.***[32]

According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject

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

[32] 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).

long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[33]

73. 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 never saw them."[34]

74. 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.

75. 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."[35] 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.

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[33] *Id.*

[34] 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)).

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

76. 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.

77. 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.

78. 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."[36] The FDA required that – going forward – opioid makers of long-acting formulations clearly communicate these risks in their labels.

79. 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

[36] 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).

information on the risk of these medications.[37]

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

B. OPIOID THERAPY MAKES PATIENTS SICKER WITHOUT LONG TERM BENEFITS

81. 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 intentionally failed to disclose the substantial scientific evidence demonstrating that chronic opioid therapy actually worsens patients' health.

82. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function on a long-term basis. 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.

83. 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 as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.[38]

84. Increasing duration of opioid use is strongly associated with an increasing

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[37] 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 September 19, 2017).

[38] 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).

prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

85. Although opioids may work acceptably well during a limited, short period of time, long-term usage results in marked declines in patient's ability to function, their 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.[39]

86. The foregoing is true both generally and for specific pain-related conditions. Studies of the long-term use of opioids for chronic lower back pain have failed 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 permit patients to return to work or physical activity. This failure is due in part to addiction and other side effects.

87. 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 than patients taking other, non-opioid medications.

C. DEFENDANTS' SCHEME TO CHANGE PRESCRIBER HABITS AND PUBLIC PERCEPTION

88. Prior to the Defendants' marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used on a short-term,

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

temporary basis in order to treat acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those limited instances, the risks of addiction are considered low or of little significance.

89. By its very nature, 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 their opioid products for both short term pain relief and for the treatment of long-term, chronic pain, they could achieve blockbuster levels of sales while exponentially increasing their profits. Further, Defendants recognized that the elevated risk of addiction associated with the long-term use of their highly-addictive, opioid products virtually guarantee that their blockbuster profits would continue indefinitely.

90. 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. In other words, Defendants needed to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

91. 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.

92. 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 and pervert medical and public perception of existing

scientific data.

93. As explained more fully herein and illustrated in Exhibit A, 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 patently false "consensus" supporting the long-term use of opioids.

D. DEFENDANTS USED "UNBRANDED" MARKETING TO EVADE REGULATIONS AND CONSUMER PROTECTION LAWS.

94. Pharmaceutical companies' promotional activity can be branded or unbranded; unbranded marketing typically focuses on education regarding a particular disease state or treatment rather than promoting a specific drug product. By using unbranded marketing in its communications, drug companies avoid the extensive regulatory framework governing branded communications.

95. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[40] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of prescribing those drugs to their patients.

96. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") places additional

[40] 21 U.S.C. 352(a); 21 CFR 202.1(e)(6); 21 CFR 202.1(e)(3); 21 CFR 1.21(a)

restrictions on branded marketing. It prohibits the sale, in interstate commerce, of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[41] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[42] The term "accompanying" is interpreted broadly to include promotional materials – posters, websites, brochures, books, and the like – disseminated by or on behalf of the manufacturer of the drug.[43] Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

97. Branded promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated. If, upon review, the FDA determines that a drug's marketing materials are misleading, it can issue either an untitled letter or a warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

98. Defendants generally avoided using branded advertisements to spread their deceptive messages and claims regarding opioids. Defendants intentionally avoided branded promotional materials for the express purpose of escaping regulatory review of their claims.

99. Instead, Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated and unbranded marketing materials – materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Defendants presented information and instructions concerning opioids

[41] 21 U.S.C 352(f); 21 U.S.C. 352(q); *U.S. v. Sullivan*, 68 S.Ct. 331, 335 (1948)
[42] 21 U.S.C.A. § 321(m)
[43] *Kordel v. U.S.*, 69 S. Ct. 106, 110 (1948)

generally that were false and misleading.

100. By acting through third parties, Defendants were able to give the false appearance that their messages reflected the views of independent third parties. Later, Defendants would cite to these sources as "independent" corroboration of their own statements. Further, as one physician adviser to Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not "push back" at having materials, for example, from the non-profit American Pain Foundation ("APF") on display in their offices, as they would with drug company pieces.

101. As part of their marketing scheme, Defendants spread and validated their deceptive messages through the following unbranded vehicles ("the Vehicles"): (i) so- called "key opinion leaders" (*i.e.*, physicians who influence their peers' medical practice, including but not limited to prescribing behavior) ("KOLs"), who wrote favorable journal articles and delivered supportive CMEs; (ii) a body of biased and unsupported scientific literature; (iii) treatment guidelines; (iv) CMEs; and (v) unbranded patient education materials disseminated through groups purporting to be patient-advocacy and professional organizations ("Front Groups"), which exercised their influence both directly and indirectly through Defendant-controlled KOLs who served in leadership roles in these organizations.

102. Defendants disseminated many of their false, misleading, imbalanced and unsupported messages through the Vehicles because they appeared to uninformed observers to be independent. Through unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.

103. Even where such unbranded messages were disseminated through third-party vehicles, Defendants adopted these messages as their own when they cited to, edited, approved,

and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. As described herein, Defendants' sales representatives distributed third-party marketing material to Defendants' target audience that was deceptive.

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

105. The unbranded marketing materials that Defendants assisted in creating and distributing either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks.

a. ***Defendants' Misuse of KOLs***

106. Defendants cultivated a select circle of doctors who were chosen and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids. As set forth herein and as depicted in Exhibit A, pro-opioid doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid doctors have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged 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 exert control of each of these modalities through their KOLs.

107. In return for their pro-opioid advocacy, Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish.

108. Defendants cited and promoted their KOLs and studies or articles by their KOLs to broaden the chronic opioid therapy market. By contrast, Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy.

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

110. In their promotion of the use of opioids to treat chronic pain, Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and Defendants.

b. ***Defendants' Corruption of Scientific Literature***

111. 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 and as depicted in Exhibit A, 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.

112. 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.

113. 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.

114. 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.

115. 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 also cited two CME programs sponsored by Endo. Defendants and those acting on their behalf failed to reveal that this "article" was 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 patients[1] 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.

116. 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 followed, for how long. None of these serious limitations were 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.

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

118. 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.

119. 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 alter, and did alter, prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

c. ***Defendants' Misuse of Treatment Guides***

120. 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.

i. <u>FSMB</u>

121. 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.

122. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 edition of the guidelines, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies" and taught that opioids were "essential" for the treatment of chronic pain, including as a first prescription option, rather than that opioids could be appropriate in limited cases after other treatments had failed. 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 Lackawanna County.

123. 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 those in Lackawanna County.

124. 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 medical education (CME) activity for prescribers of opioid medications."

125. In 2007, for example, Cephalon sponsored and distributed through its sales representatives FSMB's *Responsible Opioid Prescribing*, which was drafted by Defendant Dr. Fishman. Dr. Fishman was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Dr. Fishman's work was reviewed and

approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

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

127. 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.

ii. AAPM/APS GUIDELINES

128. 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.[44] The Chair of the committee that issued the statement, Dr. J. David Haddox,

[44] Haddox J., et al., The Use of Opioids for the Treatment of Chronic Pain – A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society, 6(1) Pain Forum 77-79 (1997)

was at the time a paid speaker for Purdue. The sole consultant to the committee was Defendant Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

129. 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 Defendant Dr. Portenoy and Defendant Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

130. 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 in Lackawanna County during the relevant time period, and were and are available online.

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

iii. GUIDELINES THAT DID NOT RECEIVE DEFENDANTS' SUPPORT

132. 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.

133. 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."[45]

134. 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 evidence that harms and costs exceed benefits based on limited evidence."[46]

135. 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.[47]

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[45] 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).

[46] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids* (2011).

[47] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf (accessed September 19, 2017).

d. *Defendants' Misuse of CMEs*

136. A CME (an acronym for "Continuing Medical Education") is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because KOLs typically teach CMEs, and are highly respected in their fields and thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

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

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

139. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that

"[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[48]

140. Lastly, KOL Defendant Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski, M.D., and Michael J. Brennan, M.D. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009.[140] It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer or non-cancer related has limited utility," and recommended dispensing "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," Actiq, and "fentanyl buccal table," Fentora, including in patients with chronic non-cancer pain. Dr. Miaskoski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on Cephalon's speaker's bureau.[49] Dr. Fine also received funding from Cephalon for consulting services.

141. Lackawanna County physicians attended or reviewed Defendants' sponsored CMEs during the relevant time period and were misled by them.

142. By sponsoring CME programs put on by Front Groups like APF, AAPM and others, Defendants could rely upon instructors to deliver messages favorable to them, as these organizations were dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing

[48] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).
[49] 14 of 21 panel members who drafted the AAPM/APS Guidelines received support from Janssen, Cephalon, Endo, and Purdue.

purpose in supporting them.

e. ***Defendants' Misuse of Patient Education Materials and Front Groups***

143. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[50] Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[51] Recognizing this phenomenon, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

144. Defendants entered into arrangements with numerous Front Groups (*i.e.*, groups purporting to be patient-advocacy and professional organizations) to promote the prescription of opioids for the treatment of chronic pain. These organizations depend, in some cases exclusively but in all cases largely, upon Defendants for significant funding and, in some cases, for their continued survival. They were involved not only in generating promotional materials and programs for doctors and patients that supported chronic opioid therapy, but they also assisted Defendants' marketing efforts in other ways—for example, by responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused

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

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

exclusively on the use of opioids to treat chronic pain. Defendants created a symbiotic relationship with the Front Groups whereby Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages. In turn, the supportive messages drove prescriptions and profits for Defendants and ensured continued funding of the Front Groups.

i. AMERICAN PAIN FOUNDATION

145. The most prominent and effective of Defendants' Front Groups was the American Pain Foundation ("APF"), which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

146. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain treatment and minimized their risks, specifically the risk of addiction. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to "educate" patients about their "right" to pain treatment with opioids. All of the programs and materials were intended to, and did, reach a national audience, including residents of Lackawanna County.

147. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. APF board member, Dr. Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

148. While APF held itself out as an independent patient advocacy organization, it simultaneously engaged in grassroots lobbying against various legislative initiatives that might regulate the prescription of opioids and protect patients from the risks associated with the unnecessary prescription of highly addictive and ineffective drugs. In stark contrast to its stated purpose, APF functioned principally as an advocate for the interests of Defendants, not patients.

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

150. The intimate relationship between APF and Defendants demonstrates APF's clear lack of independence in its finances, management, and mission, and its willingness to allow Defendants to control its activities and messages strongly indicates that each Defendant that provided it with funding was able to exercise editorial control over its publications.

151. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links - financial and otherwise - between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately."[52]

ii. THE AMERICAN ACADEMY OF PAIN MEDICINE

152. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and sponsored and hosted CMEs essential to Defendants' deceptive marketing scheme.

153. 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

[52] William Heisel, USC Annenberg Center for Health Journalism, Antidote: Investigating Untold Health Stories, *Journalists Bag a Big One: The American Pain Foundation*, https://www.centerforhealthjournalism.org/blogs/2012/05/14/journalists-bag-big-one-american-pain-foundation (accessed September 19, 2017).

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

154. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs and Defendants, Dr. Fine, Dr. Portenoy, and Dr. Webster. Dr. Webster was elected president of AAPM while under a DEA investigation. Another past AAPM president, Defendant 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."[53]

155. AAPM's staff understood that 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.

E. DEFENDANTS ACTED IN CONCERT WITH KOLs AND FRONT GROUPS TO CREATE, PROMOTE, AND CONTROL UNBRANDED MARKETING

156. Like the tobacco companies that engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the industry-funded and directed Front Groups and KOLs to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superior efficacy of opioids to treat chronic pain.

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[53] *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), http://www.medscape.org/viewarticle/500829 (accessed September 19, 2017).

157. 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. Despite knowing that this information was false and misleading, Defendants, Front Groups, and KOLs disseminated these misrepresentations nationwide, including to Lackawanna County prescribers and patients.

158. One Vehicle for Defendants' marketing collaboration was the Pain Care Forum ("PCF"). PCF 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."

159. 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.

160. 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.[54] This was critical because a REMS that went too far in narrowing the uses or benefits or in highlighting the

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[54] 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.

risks of chronic opioid therapy would undermine Defendants' marketing efforts and adversely affect profits. 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, rather than undermine, their deceptive marketing of opioids for chronic pain treatment.

F. DEFENDANTS' MISREPRESENTATIONS

161. 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 payors in Lackawanna County. These promotional messages were intended to and did encourage patients to request, doctors to prescribe, and payors to pay for chronic opioid therapy.

162. Recognizing that Doctors are the gatekeepers for controlling access to prescription drugs, not surprisingly, Defendants focused the bulk of their marketing efforts and multi-million dollar budgets on the professional medical community. As a controlled substance with significant regulatory barriers limiting access, Defendants knew doctors would not prescribe opioids to patients with common chronic pain complaints unless doctors were convinced that opioids had real benefits and minimal risks. Accordingly, Defendants concealed from prescribers, patients, and the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Instead, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, Lackawanna County doctors began prescribing opioids on a long-term to treat chronic pain – a treatment choice that most if not all never would have considered prior to Defendants'

campaign.

163. Drug company marketing materially impacts doctors' prescribing behavior.[55] 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. Evidence shows that Doctors who would otherwise not have prescribed opioids were, in fact, induced by Defendants' deceptive marketing to prescribe opioids for chronic pain as a result of Defendants' deceptive marketing.

164. 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, 88% of the practitioner respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities.[56] These results are the direct consequence of Defendants' fraudulent marketing campaign.

165. As described in detail below, Defendants:

- Misrepresented the truth about how opioids lead to addiction;
- Misrepresented that opioids improve function;
- Misrepresented that addiction risk of opioids can be managed;

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[55] 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 1997to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

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

- 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 to patients;
- Falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

166. Defendants' misrepresentations were aimed at doctors, patients, and payors.

167. 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 existed.[57]

a. ***Defendants, Acting Individually and Collectively, Misrepresented the Truth About How Use of Opioids Leads to Addiction.***

168. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. Through their well-funded, comprehensive, and aggressive marketing efforts, Defendants succeeded in changing the perceptions of many physicians, patients, and health care payors and persuaded them that opioid addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for chronic pain. As both an intended and foreseeable result, doctors in Lackawanna County prescribed more opioids to more patients – thereby enriching Defendants.

169. Each of the Defendants claimed that the potential for addiction from its drugs was relatively small or non-existent, despite the complete lack of supporting scientific evidence.

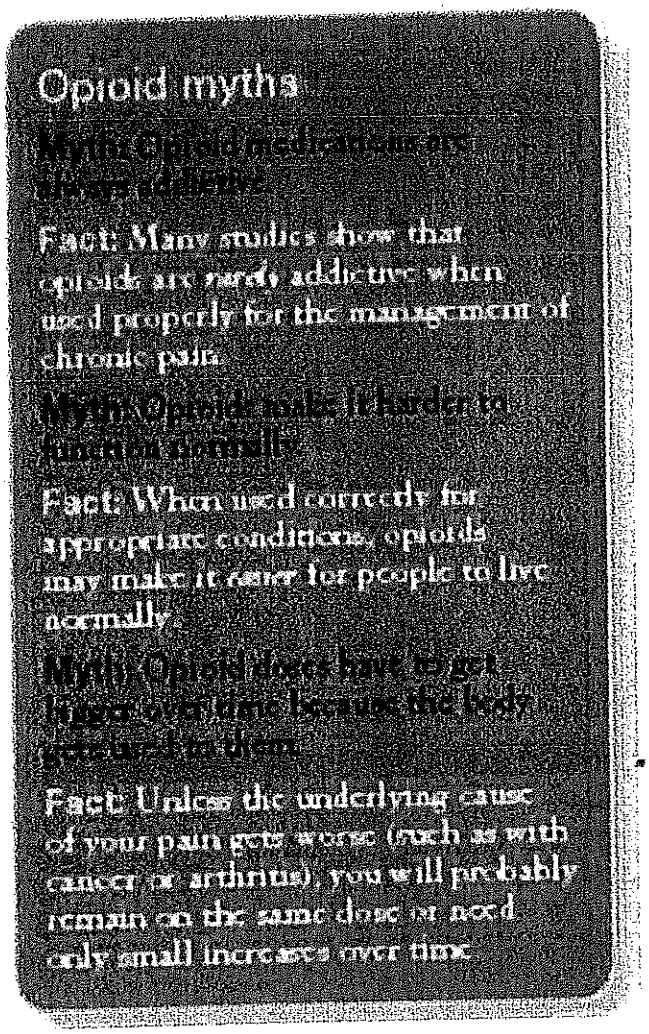
[57] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

170. To wit, Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which fraudulently claimed that addiction is rare and limited to extreme cases of unauthorized dose escalations, opioid prescription fraud, or theft.

171. Similarly, Endo sponsored a website, www.painknowledge.com, through APF, which falsely claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician.

172. Additionally, Endo distributed a patient education pamphlet edited by KOL Defendant Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that patients prescribed opioids for *genuine* pain will not become addicted, a claim which is both unsupported and known to be false.

173. Likewise, Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF , which, as set forth in the excerpt below, described the fact that opioids are addictive as a "myth" and falsely asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."



Although the term "rarely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician, which is untrue. The guide states as a "fact" that "Many studies" show that opioids are *rarely* addictive when used for chronic pain. In fact, no such studies exist.

174. For another example, Purdue sponsored and Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid

pain medications," although the term "very unlikely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial.

175. For another example, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids would become addicted.[58] This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

176. In Addition, in the 1990s, Purdue amplified the pro-opioid message with promotional videos and featuring Dr. Portnoy and other doctors in which it was claimed, "the likelihood that treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[59]

177. As yet another example from the industry, Actavis's strategy and pattern of deceptive marketing is similarly evident in its internal training materials. A sales education module titled "Kadian Learning System" trained Actavis's sales representatives on the marketing messages described above – including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in Lackawanna County.

178. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality,

[58] In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.
[59] Excerpts from one such video, including the statement quoted here, may be viewed at http://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (accessed September 19, 2017).

available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids. First, Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have necessitated increasing doses: "Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [Chronic pain]." Second, Actavis instructed its sales personnel that opioid "[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose." Actavis failed to inform doctors, via its sales representatives, of the greater risks associated with opioids at high doses.

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

180. Finally, the internal documents of another Defendant, Endo, indicate that

pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines with doctors during detailing visits. These guidelines deceptively concluded that the risk of addiction is manageable for patients, regardless of past abuse histories, amongst other deceptive statements as described above.

181. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables: they suggested that doctors who *failed* to treat their patients' chronic pains with opioids were failing their patients and risking professional discipline, while doctors who prescribed long-term opioid therapy were following the compassionate (and professionally less risky) approach. Defendants claimed that "exaggerated" concerns about the risk of addiction resulted in patients' pain being under- treated while opioids were over-regulated and under-prescribed. The Treatment Options guide funded by Purdue and Cephalon claims that "[d]espite the great benefits of opioids, they are often underused." The APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, laments that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include . . . misconceptions about opioid addiction."[60]

182. *Let's Talk Pain*, sponsored by APF, AAPM and Janssen, likewise warns, "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say, "[b]ecause of the potential for abusive and/or addictive behavior, many health care professionals have been reluctant to prescribe opioids for their patients.... This

[60] This claim also appeared in a 2009 publication by APF, *A Reporter's Guide*.

prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

b. ***Defendants, Acting Individually and Collectively, Misrepresented That Opioids Improve Function.***

183. Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or prescribing supplemental short-acting opioids to take on an as- needed basis for breakthrough pain.

184. Although opioids may initially improve patients' function by providing pain relief in the short term, no controlled studies of the use of opioids beyond 12 weeks has ever shown that opioids improve patients' function in the long-term. On the contrary, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[61] Despite this lack of evidence of improved function, and the existence of evidence to the contrary, Defendants consistently promoted opioids as capable of improving patients' function and quality of life without disclosing the lack of evidence for this claim.

185. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."[62]

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[61] Jeffrey Dersh, et al., Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders, 33(20) Spine 2219-27 (Sept. 15,2008).

[62] Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, *King Pharmaceuticals*, Re: NDA21-260 (March 24, 2008).

186. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007), sponsored by drug companies including Cephalon, Endo and Purdue, deceptively taught that relief of pain in itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

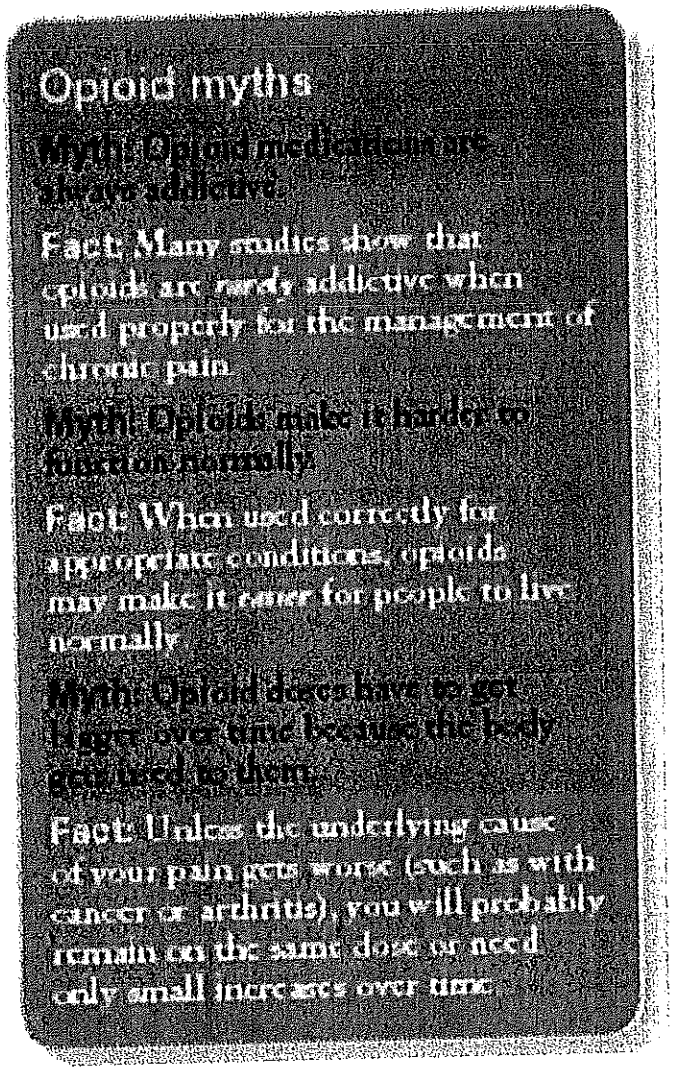
187. Cephalon and Purdue sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The Treatment Options guide notes that non-steroidal anti-inflammatory drugs (*e.g.*, Aspirin or Ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids. The APF distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report, and it is currently still available online.

188. Through the APF, Endo sponsored a website, painknowledge.com, which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life as well as "improved function" as benefits of opioid therapy.

189. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

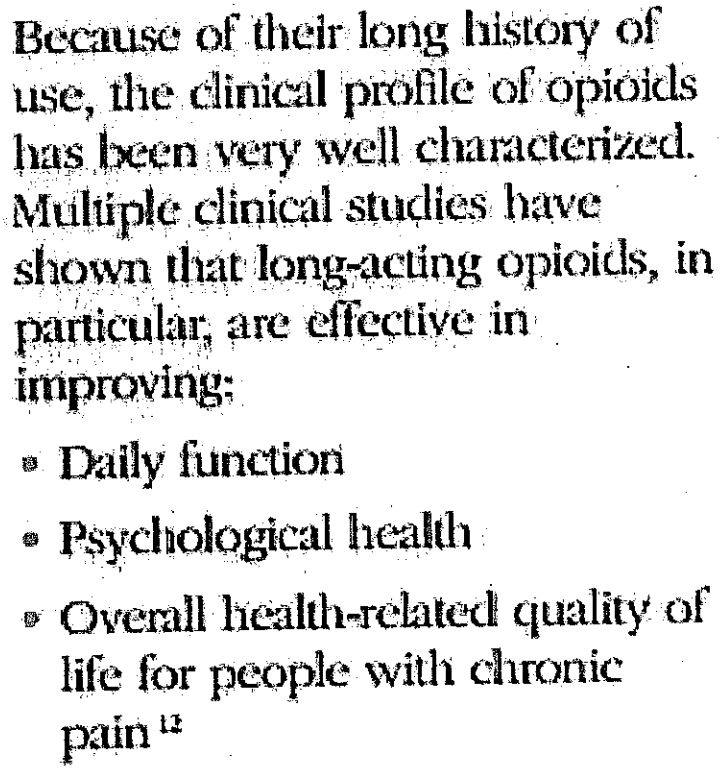
190. As set forth in the excerpt below, the guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. The targeting of older adults also

ignored heightened opioid risks in this population.



191. Janssen sponsored a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and American Society for Pain Management Nursing whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative despite the lack of statistical support.

192. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients," with the implication these studies presented claims of long-term improvement.



Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain [12]

The sole reference for the functional improvement claim 1.) noted the absence of long-term studies and 2.) actually stated, "For functional outcomes, the other analgesics were significantly more effective than were opioids."

193. Purdue sponsored and Janssen provided grants to APP to distribute *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning" (emphasis in the original).

c. ***Defendants, Acting Individually and Collectively, Misrepresented that Addiction Risk can be Effectively Managed***

194. Defendants each continue to maintain to this day that most patients can safely take opioids long-term for chronic pain relief without becoming addicted. Presumably to explain to doctors the high incidence of patient opioid addiction, Defendants have recently acknowledged that some patients could become addicted, but that doctors can effectively avoid or manage that risk by using screening tools or questionnaires. These tools, they claim, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) and allow doctors to more closely monitor patients at greater risk of addiction.

195. There are three fundamental flaws in Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that the addiction risk screening tools currently available are reliable, effective, capable of being applied correctly and consistently, or invulnerable to patient manipulation. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through the screening tools can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients identified through such screening tools as "low risk" can take opioids long-term without significant danger of addiction.

196. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. An Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring

instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[63] Furthermore, attempts to treat high-risk patients, like those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening tests are not proven to work in the real world, even when the most well-intentioned doctors were misled to employ them.[64]

197. Defendants' misrepresentations regarding the risk of addiction from chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors (collectively "GPs"), who treat many chronic conditions but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. One study conducted by pharmacy benefits manager Express Scripts concluded, after analyzing 2011-2012 narcotic prescription data of the type regularly used by Defendants to market their drugs, that only 385 of the more than half million prescribers of opioids during that time period were identified as pain specialists.[65]

198. In materials they produced, sponsored, or distributed, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain. Defendants' marketing scheme contemplated a "heads we win; tails we win" outcome: patients deemed low risk were to receive opioids on a long-term basis without enhanced monitoring, while patients deemed high risk were

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[63] The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain, Agency for Healthcare Res. & Quality (Sept. 19, 2014).

[64] M. Von Korff, et al., *Long-term opioid therapy reconsidered*, 15595, Annals Internal Med. 325 (Sept. 2011); L. Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 Pain Physician S1 (2012).

[65] Express Scripts Lab, A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain (December 2014).

also to receive opioids on a long- term basis but with more frequent visits, tests and monitoring – with those added visits, tests, and monitoring to be paid for or reimbursed by payors, including Plaintiff. This, of course, led to a "heads you lose; tails you lose" outcome for patients – all of whom are subjected to an unacceptable risk of addition – and for payors, including Plaintiff.

199. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

200. Endo paid for a 2007 supplement available for continuing education credit in the Journal of Family Practice written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by Defendant Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. Purdue sponsored a 2011 webinar taught by Defendant Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

d. ***Defendants, Acting Individually and Collectively, Misled Physicians, Patients, and Payors Through the Use of the Term "Pseudoaddiction."***

201. Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe ever more opioids despite signs that the patient was addicted. The word "pseudoaddiction" was concocted by Dr. J. David

Haddox, who later went to work for Purdue, and was popularized in opioid therapy for chronic pain by Defendant Dr. Portenoy, who consulted for Defendants Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction" – as if patients could not experience both.

202. In the materials they produced, sponsored, or controlled, Defendants misrepresented that the concept of "pseudoaddiction" is substantiated by scientific evidence.

203. Cephalon and Purdue sponsored the Federation of State Medical Boards' 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, which are in fact signs of genuine addiction, are all really signs of "pseudoaddiction."

204. Purdue did not mention that the author who concocted both the word and the phenomenon it purported to describe became a Purdue Vice President; nor did Purdue disclose the lack of scientific evidence to support the existence of "pseudoaddiction."[66]

205. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, PartnersAgainstPain.com, in 2005, and upon information and belief circulated this pamphlet after 2007. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but rather was indicative of "pseudoaddiction" caused by untreated pain. It also stated, "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated . . . . Even such

[66] J. David Haddox & David E. Weissman, *Opioid pseudoaddiction – an iatrogenic syndrome*, 36(3) Pain 363 (Mar. 1989).

behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

e. ***Defendants, Acting Individually and Collectively, Claimed Withdrawal is Simply Managed.***

206. In an effort to underplay the risk and impact of addiction, Defendants claimed that, while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed, if and when pain relief is no longer desired, by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids – an adverse effect that also makes it less likely that patients will be able to stop using drugs.

207. In materials Defendants produced, sponsored, and/or controlled, Defendants made misrepresentations to persuade doctors and patients that withdrawal from their opioids was not a problem and they should not be hesitant about prescribing or using opioids. These claims were not supported by scientific evidence.

208. A CME sponsored by Endo entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering a patient's opioid dose by 10% to 20% per day for ten days. This claim was misleading because withdrawal in a patient already physically dependent would take longer than ten days – when it is successful at all.[67]

209. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its*

[67] See Jane Ballantyne, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain with Opioids*, 21(5) Pain Clinical Updates (Dec. 2013).

Management, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

f. *Defendants, Acting Individually and Collectively, Misrepresented that Increased Doses Pose no Significant Additional Risks.*

210. Defendants claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.

211. In materials Defendants produced, sponsored or controlled, Defendants instructed patients and prescribers that patients could remain on the same dose indefinitely, assuaging doctors' concerns about starting patients on opioids or increasing their doses during treatment, or about discontinuing their patients' treatment as doses escalated. These claims were not supported by scientific evidence.

212. 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 taught that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the true figure was closer to 3,200 at the time.[68]

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[68] Robert E. Tarone, et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

213. Cephalon sponsored a CME written by KOL Defendant Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

214. Endo sponsored a website, *painknowledge.com*, through APF, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

215. Endo distributed a patient education pamphlet edited by KOL Defendant Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was published 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."

216. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high-dose opioids. This publication is still available online.

217. Purdue sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME was edited by KOL Defendant Dr. Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

g. ***Defendants, Acting Individually and Collectively, Deceptively Omitted or Minimized the Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment.***

218. In materials they produced, sponsored or controlled, Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that

prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. None of these claims was supported by scientific evidence.

219. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[69] hormonal dysfunction;[70] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[71] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety. Post-traumatic stress disorder and anxiety also often accompany chronic pain symptoms.[72]

220. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the figure is closer to 3,200.[73] *Treatment Options* also warned that risks of NSAIDS increase if "taken for more than a period of months," with no corresponding warning about opioids.

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[69] 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).
[70] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001).
[71] Bernhard M. Kuschel, The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study, Eur. J. Pub. H. (July 31, 2014).
[72] Karen H. 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- 47 (2012).
[73] Robert E. Tarone, et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

221. Endo sponsored a website, painknowledge.com, through APF, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects that omitted significant adverse effects including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

222. Janssen and Purdue sponsored and Endo provided grants to APF to distribute *Exit Wounds* (2009), which omits warnings of the risk of potentially fatal interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder.

223. As a result of Defendants' campaign of deception, promoting opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[74]

G. DEFENDANTS' PROMOTION OF THEIR BRANDED DRUGS WAS ALSO DECEPTIVE.

224. 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

[74] M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51*(10)* Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. *See also* J. Mafi, *et al.*, *Worsening Trends in the Management and Treatment of Back Pain,* 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and in Lackawanna County. 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.

225. 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 Lackawanna County.

H. DEFENDANTS KNEW THAT THEIR MARKETING OF CHRONIC OPIOID THERAPY WAS FALSE, UNFOUNDED, AND DANGEROUS AND WOULD HARM PLAINTIFF AND ITS RESIDENTS.

226. 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.

227. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and payors to pay for their opioids for chronic pain.

228. 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.

I. DEFENDANTS FRAUDULENTY CONCEALED THEIR MISREPRESENTATIONS

229. Defendants took steps to avoid detection of, and to fraudulently conceal, their deceptive marketing and conspiratorial behavior.

230. Defendants disguised their own roles in the deceptive marketing by funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of Defendants' false and misleading statements about opioid use for chronic pain. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Defendants exerted their considerable influence on these purportedly "educational" or "scientific" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not public.

231. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear these items were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions the materials did no support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions. The false and misleading nature of Defendants' marketing was not known to, nor could it reasonably have been discovered by, Plaintiff or its residents.

232. Defendants also concealed their participation by extensively using the public relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.

233. Defendants concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the existence of claims that Plaintiff now asserts. Plaintiff did not discover the existence and scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through the public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put them on notice of potential claims.

J. DEFENDANTS ENTERED INTO AND ENGAGED IN A CIVIL CONSPIRACY

234. 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.

235. 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.

236. This network is interconnected and interrelated, as demonstrated by Exhibit A, which is incorporated herein, 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 and medical providers of the appropriate uses, risks and safety of opioids.

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

K. DISTRIBUTOR DEFENDANTS INTENTIONALLY FAILED TO TAKE ANY ACTION TO STOP THE MISUSE OF OPIOIDS, IN VIOLATION OF STATE AND FEDERAL LAWS AND REGULATIONS

238. The Distributor Defendants purchased opioids from manufacturers, such as the named Manufacturer Defendants herein, and sold them to pharmacies throughout Lackawanna County.

239. The Distributor Defendants played an integral role in the chain of opioids being distributed throughout Lackawanna County.

240. The Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, 35 Pa.C.S.A. § 780-112(c), via 21 CFR § 1301.74(b), requires the Distributor Defendants to "design and operate a system to disclose . . . suspicious orders of controlled substances. . . . Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," which was intentionally and willfully ignored by the Distributor

Defendants.

241. The Distributor Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the DEA.

242. The Distributor Defendants were each on notice that the controlled substances they distributed or prescribed were the kinds that were susceptible to diversion for illegal purposes, abused, overused, and otherwise sought for illegal, unhealthy and problematic purposes.

243. The Distributor Defendants were each on notice that there was an alarming and suspicious rise in distributing opioids within Lackawanna County during the time periods relevant in this claim.

244. The Distributor Defendants knew or should have known that they were supplying vast amounts of dangerous drugs in Lackawanna County that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

245. The Distributor Defendants intentionally failed in their duty to take any action to prevent or reduce the distribution of these drugs for the purpose of their own massive profits.

246. The Distributor Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the flow of opioid drugs into Lackawanna County.

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

248. The Distributor Defendants have displayed a continuing pattern of failing to submit suspicious order reports.

249. In 2008, McKesson paid a $13.25 million fine to settle similar claims regarding

suspicious orders from internet pharmacies.[75]

250. Despite these prior penalties, McKesson's pattern of failing to report suspicious orders continued for many years.

251. According to the DEA, McKesson "supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills" during the time in question, and "frequently misused products that are part of the current opioid epidemic."[76]

252. On January 17, 2017, the DEA announced that McKesson had agreed to pay a record $150 million fine and suspend the sale of controlled substances from distribution centers in several states.[77]

253. In 2008, Defendant Cardinal paid a $34 million penalty to resolve allegations that it failed to report suspicious opioid orders.[78]

254. Despite this past penalty, in 2017, it was announced that Defendant Cardinal agreed to a $44 million fine to "resolve allegations that it failed to alert the Drug Enforcement Agency to suspicious orders of powerful narcotics by pharmacies in Florida, Maryland, and New York.[79]

255. Defendant Amerisource faced a criminal inquiry "into its oversight of painkiller sales" in 2012.[80] They have paid out fines for similar claims to the state of West Virginia.

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[75]Sam Owens, *'Suspicious' drug order rules never enforced by state*, http://www.wvgazettemail.com/news-health/20161218/suspicious-drug-order-rules-never-enforced-by-state, (posted December 18, 2016, accessed September 20, 2017).

[76]DOJ, *McKesson Agrees to Pay record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders, (posted January 17, 2017, accessed September 20, 2017).

[77] *Id.*

[78]DOJ, *United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties under the Controlled Substances Act*, https://www.justice.gov/usao-wdwa/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under-0, (posted December 23, 2016, accessed September 20, 2017).

[79] Lenny Bernstein, et al, https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.3156f3e6fe75, (accessed on September 20, 2017).

[80] Barry Meier, *Walgreen to Pay $80 Million Fine in D.E.A. Inquiry*, http://www.nytimes.com/2013/06/12/business/walgreen-to-pay-80-million-settlement-over-painkiller-sales.html

256. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, including into Lackawanna County.

257. The Distributor Defendants are also 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."

258. Between the years in question, including 2007 through 2016, the Distributor Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into Lackawanna County.

259. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.

260. The sheer volume of the increase in opioid pain medications, including OxyCodone, being distributed to retailers, should have put the Distributor Defendants on notice to investigate and report such orders.

261. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers in Lackawanna County.

262. Upon information and belief, the Distributor Defendants did not refuse to ship or supply any opioid medications to any pharmacy in Lackawanna County from 2007 to the present.

(accessed on September 20, 2017).

263. The Defendant Distributors knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of Lackawanna County.

264. The Defendant Distributors also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications within Lackawanna County.

265. The Distributor Defendants made substantial profits from the opioids sold in Lackawanna County.

266. The Distributor Defendants violated the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act and related Federal Regulations for distributors, including the aforementioned section, by failing to properly report suspicious orders.

267. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of the residents of Lackawanna County.

268. By the actions and inactions described above, the Distributor Defendants caused great harm to the County of Lackawanna.

FIRST CAUSE OF ACTION
DECEPTIVE ACTS OR PRACTICES
PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW 73 Pa.C.S.A. § 201-1, *et seq.*
(AGAINST ALL DEFENDANTS)

269. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

270. Defendants violated the Pennsylvania Unfair Trade Practices and Consumer Protection Law (73 Pa.C.S.A. § 201-1, *et seq.*), because they engaged in deceptive acts or practices in the conduct of business, trade or commerce within Pennsylvania and Lackawanna County in violation of 73 Pa. Stat. Ann § 201-4(i-xxi), including:

- Marketing opioid drugs as safe and effective for the long term treatment of chronic pain conditions when they were not for the

purpose of deceiving physicians into using addictive opioids;

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of Pennsylvania and Federal law;
- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- Holding themselves out as law-abiding distributors but instead

withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating Pennsylvania and Federal law by not reporting these doctors instead; and,

271. Defendants knew at the time that they made their misrepresentations and omissions that 1.) they were false and 2.) had the tendency to influence the consumer choices of Plaintiff and its residents.

272. Defendants designed their misrepresentations and omissions for the purpose of influencing Plaintiff and its residents into relying upon them.

273. Defendants' consistent, deceptive representations that their opioids had properties unsupported by medical literature did in fact deceive Plaintiff and its residents, causing them to both prescribe and consume opioids for the treatment of chronic pain conditions and suffer from addiction when they otherwise would not.

274. Given the incredible resources Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions, as stated above.

275. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.

276. Plaintiff and its residents have been injured by reason of Defendants' violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law directly caused by

Defendants' deceptive behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.

SECOND CAUSE OF ACTION
FRAUD
(AGAINST ALL DEFENDANTS)

277. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

278. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:

- Marketing opioid drugs as safe and effective for the long term treatment of chronic pain conditions when they were not for the purpose of deceiving physicians into using addictive opioids;
- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations

in violation of Pennsylvania and Federal law;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- Holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating Pennsylvania and Federal law by not reporting these doctors instead; and,

279. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

280. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

281. Given the incredible resources Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions, as stated above.

282. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.

283. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.

284. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

THIRD CAUSE OF ACTION
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

285. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

286. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint above, Defendants have profited and benefited from opioid purchases made by Plaintiff and its residents.

287. In exchange for the opioid purchases, and at the time Plaintiff and its residents made these payments, Plaintiff and its residents expected that Defendants had provided all of the necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

288. Defendants wrongdoing directly caused Plaintiff to suffer increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue, without receiving any of the purported benefits deceptively promoted by Defendants.

FOURTH CAUSE OF ACTION
NEGLIGENCE
(AGAINST DISTRIBUTOR DEFENDANTS)

289. Plaintiff incorporates the allegations within all prior paragraphs of this Complaint as if they were fully set forth herein.

290. Distributor Defendants have a duty to exercise reasonable care in the distribution of opioids, as provided by state and federal law, to avoid, prevent, or attenuate third-party misconduct.

291. Distributor Defendants breached this duty by failing to take any action to prevent or reduce the distribution of opioids, as required by state and federal law, and instead participated in and enabled Defendants' misconduct.

292. As a proximate result, Distributor Defendants and its agents have caused Plaintiff to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, the County has borne the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, law enforcement services, and child and family services for County Residents and using County resources in relation to opioid use and abuse. Additionally, the County has suffered lost productivity from its workforce, thereby losing much needed tax revenue.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(AGAINST ALL DEFENDANTS)

293. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

294. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:

- Marketing opioid drugs as safe and effective for the long term treatment of chronic pain conditions when they were not for the purpose of deceiving physicians into using addictive opioids;
- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- Disseminating misleading statements regarding the true risk of addiction and promoting the concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of Pennsylvania and Federal law;
- Endorsing and assisting in the distribution of CMEs containing statements concerning the use of opioids to treat chronic non-cancer pain;
- Developing and disseminating misleading scientific studies that concluded opioids are safe and effective for the long-term

treatment of chronic non-cancer pain and that opioids improve quality of life, based upon inadequate data while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained statements concerning the use of opioids to treat chronic non-cancer pain;
- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- Exclusively disseminating statements in education materials to hospital doctors and staff not supported by valid, balanced data while purportedly educating them on new pain standards;
- Making statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- Withholding from law enforcement the names of prescribers they believed to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating Pennsylvania and Federal law by not reporting these doctors instead; and,

295. Defendants should have known at the time that they made their misrepresentations and omissions that they were false.

296. Defendants should have, at the least, investigated the truth or falsity of their representations to Plaintiff.

297. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

298. Given the incredible resources Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions, as stated above.

299. Given the infinitely better-resourced and highly sophisticated nature of the

Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.

300. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.

301. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

PRAYER FOR RELIEF

WHEREFORE Plaintiff demands judgment against Defendants, jointly and severally, awarding Plaintiff:

i. Compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;

ii. Damages, treble damages, costs, and reasonable attorney's fees pursuant to 73 P.S. § 201-9.2;

iii. Punitive damages;

iv. Interest, costs, and disbursements; and,

v. Such other and further relief as this Court deems just and proper.

Dated: September 25, 2017

Respectfully Submitted,

/s/Joseph Cappelli

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Attorneys for Plaintiff

VERIFICATION

I, Joseph Cappelli, Esquire being duly sworn according to law, depose and say that I am the attorney for the Plaintiff and that I make this pleading on his behalf, that he is unavailable to execute a Verification so as to enable timely filing of Plaintiff's Complaint and the facts set forth in the foregoing Complaint are true and correct to the best of counsel's knowledge, information and belief.

This Verification is made pursuant to Pa. R.C.P. 1024 and is based on interviews, conferences, reports, scientific research, records and other investigatory material in the file.

Dated: September 25, 2017

/s/ Joseph Cappelli

Attorney for Plaintiff