IN THE CIRCUIT COURT OF COOK COUNTY
COOK COUNTY, ILLINOIS

THE PEOPLE OF THE STATE OF ILLINOIS, and COOK COUNTY, ILLINOIS

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; PERRY FINE; SCOTT FISHMAN; and LYNN WEBSTER

Defendants.

Index No.

COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs, the People of the State of Illinois ("the People of Illinois") and Cook County, Illinois ("Cook County" or "the County") (collectively "Plaintiffs"), by and through the undersigned attorneys, for their Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Abbott Laboratories, Abbott Laboratories, Inc., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Endo Health Solutions Inc., Endo Pharmaceuticals, Inc.,

Perry Fine, Scott Fishman, and Lynn Webster (collectively, "Defendants") allege as follows:

INTRODUCTION

1. Plaintiffs spend 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. Plaintiffs also provide a wide range of other services on behalf of their residents, including services for families and children, public assistance, emergency and ambulatory services, and law enforcement.

3. Plaintiff Cook County contains 30 townships and 130 municipalities, with the Town of Cicero operating as both a township and municipality. The City of Chicago voted to eliminate township government in 1902, thereby transferring those responsibilities to the City. Evanston, Illinois voted to do the same in 2014. In total, Cook County encompasses all or part of 23 cities and 111 villages, 1 town, and 6 unincorporated communities. Plaintiff employs approximately 22,000 people. Plaintiff provides group health insurance to its employees by paying the lion's share of premium for such employees. Plaintiff also funds workers compensation and provides disability care programs for its employees participating in the healthcare plan.

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

5. 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.

6. "Addiction" encompasses 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 spectrum.

7. 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").

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

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

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

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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).

11. 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.

12. 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.

13. 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.

14. 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.

15. 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 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

[3] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: http://www.cdc.gov/drugoverdose/epidemic/index.html (accessed August 18, 2017) (internal footnotes omitted).

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

supply.[5] By 2014, nearly two million Americans either abused or were dependent on opioids.[6]

16. Defendants' campaign has been extremely profitable for them. In 2012 alone, opioids generated $8 billion in revenue for drug companies. Of that amount, $3.1 billion went to Purdue for its OxyContin sales. By 2015, sales of opioids grew further to approximately $9.6 billion.[7]

17. 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.[8]

[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 (as viewed May 10, 2016).

7 D. Crow, Drugmakers hooked on $10bn opioid habit, Financial Times (August 10, 2016). In 2015, the Sackler family, the Purdue company's sole owners, appeared at number sixteen on Forbes magazine's list of America's richest families. Available at https://www.firstthings.com/article/2017/03/american-carnage (as viewed September 27, 2017).

8 CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, supra. The opioid epidemic killed more than 33,000 people in 2015. Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015. MMWR Morb Mortal Wkly Rep 2016; 65:1445-1452. Available at: http://dx.doi.org/10.15575/mmwr.mm655051e1 (as viewed September 29, 2017).

18. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.[9] Between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[10]

19. On January 1, 2016, the Centers for Disease Control announced that "[o]pioids, primarily prescription pain relievers and heroin, are the main drugs associated with overdose deaths." Alarmingly, the CDC noted that in 2014 there were approximately one and a half times more drug overdose deaths in the United States than deaths from motor vehicle crashes.[11]

20. Opioid addiction and overdose have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."[12]

[9] 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.

[10] 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). One-third of Americans who have taken prescription opioids for at least two months say they became addicted to, or physically dependent on them. Available at https://www.washingtonpost.com/national/health-science/one-third-of-long-term-users-say-theyre-hooked-on-prescription-opioids/2016/12/09/e048d322-baed-11e6-91ee-1adddfe36cbe_story.html?utm_term=.7259d7ee60b4 (as viewed September 27, 2017).

[11] CDC, Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014. Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm (accessed Aug. 18, 2017).

[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 August 18, 2017).

21. 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]

22. 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."

23. The rising numbers of persons addicted to opioids have led to significantly 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 Illinois State and the County. Consequently, public health and safety throughout the United States, including the 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.

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

[14] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed August 18, 2017) (emphasis added).

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

24. Opioids contributed to nearly 1,200 overdose deaths in Illinois in 2016, according to data from the Illinois Department of Public Health.[16] Illinois is one of 14 states that had an 8.3% increases in overdose deaths.[17]

25. The Illinois Department of Public Health reports that more Illinoisans died from an opioid-related drug overdose (due to heroin and prescription opioid pain relievers) in 2014 than from homicide or motor vehicle accidents.[18]

26. A recent report, published through the cooperation of Cook County Department of Public Health (CCDPH), Chicago Department of Public Health (CDPH), and the Cook County Health and Hospitals System (CCHHS), illustrates the severity of the opioid problem for communities in Cook County. According to the report, in 2015, 647 overdose related deaths were documented in the County. Of which, 426 took place in Chicago with the remaining 221 being spread throughout the suburban areas.[19]

27. Based on these figures the opioid-related overdose rate in the city of Chicago was significantly higher, at 15.5 per 100,000, than the national average of 10.4 per 100,000. While the rate for the suburban portion of the county was lower than the national average at 8.8, *a larger portion of the deaths (20.4%) could be attributed to prescription opioids in the suburban areas*.[20]

28. Relatedly, CCHHS reports that CCHHS hospitals saw more than 5,000 opioid-related emergencies in 2016. This is up from just 1,000 in 2006.[21]

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[16] C. Bishchel, *The Opioid Epidemic is Worse in Deep Southern Illinois* (June 1, 2017).
[17] *Id.*
[18] Prescription Opioids and Heroin, Available at http://www.dph.illinois.gov/topics-services/prevention-wellness/prescription-opioids-and-heroin (accessed August 28, 2017).
[19] Cook County Public Health, Epidemiology Brief: Opioid-Related Overdose Deaths in Cook County, IL, 2015 (Accessed November 29, 2017).
[20] *Id.* (emphasis added)
[21] Cook County Health and Hospital System, Opioids, Available at http://www.cookcountyhhs.org/opioids/ (Accessed November 28, 2017).

29. Suburban Cook County (excluding Chicago) saw a similar increase in the number of opioid related overdose deaths (OROD), rising from 221 to 340, in 2016. Thus, the suburban rate of ORODs rose from 8.8 per 100,000 to 13.7, surpassing the previous year's national average of 10.4 per 100,000.[22]

30. Cook County Sheriff Tom Dart recently told Chicago Tonight that more than 5,000 inmates have been treated for opioid withdrawals within the last year. According to the Sheriff, since public officials have been slow to react, the jail has "adapted to this new role we have… as primary mental health providers, primary substance abuse providers".

31. As the jail adapts to its new role it has begun to offer numerous services to contend with the growing issue of opioid addiction. It provides counseling, and other services aimed at addressing the underlying issues that lead to abuse and addiction but it also tries to give inmates tool for when they get out. One such tool being the availability of naloxone kits for inmates who have been through detox. Made available upon being discharged, these kits are intended to prevent future overdoses. The sheriff's office claims 1,000 kits have been given away since 2016.[23]

32. The commission of criminal acts to obtain opioids is an inevitable consequence of opioid addiction, and Illinois counties are no exception. In a 2016 Survey of Police Chiefs and County Sheriffs by the Illinois Criminal Justice Information Authority, Illinois police chiefs and sheriffs most frequently identified heroin and

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[22] *Id.*; See also, Chicago Department of Public Health , "Epidemiology Report: Increase in overdose deaths involving opioids- Chicago 2015-2016", https://www.cityofchicago.org/content/dam/city/depts/cdph/tobacco_alchohol_and_drug_abuse/2016ChicagoOpioidReport.pdf (accessed 12/8/2017)

[23] P. Schutz, Opioid Epidemic Hits Cook County Jail, Chicago Tonight (November 29, 2017)

prescription opioids as the greatest drug threats in their jurisdictions.[24] Factors important in making this conclusion of higher threat compared to other drugs included ease of use and distribution, high availability, increased demand, and contribution to violent crime.[25]

33. The Defendants' course of conduct has violated and continues to violate state and common law as laid out herein:

a. 815 ILCS 505/1, et seq., in that defendants have engaged in a scheme to defraud the citizens of the County and engage in other acts prohibited by the Illinois Consumer Fraud Act, which conduct causes harm to the People of Illinois and the County;

b. 815 ILCS 510/1, et seq., in that Defendants have engaged in unfair acts or practices prohibited by the Illinois Deceptive Trade Practices Act, which acts cause substantial harm to the People of Illinois and the County;

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

d. The common law perpetuation of a public nuisance, in that all Defendants have engaged in an unlawful marketing scheme which has directly resulted in substantial, pervasive, and unreasonable interference with the public health;

e. The common law prohibition against civil conspiracy, in that all Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner;

f. The common law prohibition on unjust enrichment, in that all Defendants have unjustly retained a benefit to the County's detriment, and all Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

[24] Illinois Drug Threat Assessment: A Survey of Police Chiefs and County Sheriffs, Illinois Criminal Justice Information Authority, J. Maki. Available at http://www.icjia.state.il.us/assets/articles/DTA_PDF_022717.pdf (accessed August 28, 2017).
[25] *Id*.

34. A 2016 Centers for Disease Control and Prevention study estimated the national economic impact of prescription opioid overdoses, abuse and dependence to be $78.5 billion dollars annually. The study broke down the distribution of this impact further:[26]

- Lost Productivity: $42 billion (53.3%)
- Health Insurance: $26.1 billion (33.3%)
- Criminal Justice: $7.6 billion (9.7%)
- Substance Abuse Treatment: $2.8 billion (3.6%)

35. The economic impact of prescription opioid overdoses on the County is well in line with national trends. As a direct and foreseeable consequence of Defendants' egregious conduct, the County paid, and continues to pay, millions of dollars for health care costs that stem from prescription opioid dependency created by Defendants' deceptive marketing campaign. These costs include unnecessary and excessive opioid prescriptions, substance abuse treatment services, ambulatory services, emergency department services, and inpatient hospital services, among others. Defendants' conduct also caused the County to incur substantial economic, administrative and social costs relating to opioid addiction and abuse, including criminal justice costs, victimization costs, lost productivity costs, and education and prevention program costs among others. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff.

36. The County seeks a judgment requiring all Defendants to pay restitution, damages, including multipliers of damages, disgorgement, civil penalties, attorney's fees,

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

costs, and expenses, injunctive relief, and any other relief to which the County may be entitled.

JURISDICTION AND VENUE

37. This Court has personal jurisdiction over Defendants because they carry on a continuous and systematic part of their general business within Illinois, have transacted substantial business with Illinois entities and residents, and have caused harm in Illinois as a result of the specific business activities complained of herein.

38. Venue as to each Defendant is proper in this Court under 735 ILCS 5/2-101 as the transactions and occurrences that form the basis for this Complaint occurred in Cook County, Illinois.

39. There is no federal court jurisdiction in that there is not complete diversity of citizenship because Abbott is a resident of the State of Illinois and no substantial federal question is presented.

PARTIES

40. Plaintiff Cook County is organized and existing under the laws of the state of Illinois. Cook County is located in northern Illinois and contains 30 townships and 130 municipalities. It encompasses all or part of twenty-three cities and 111 villages, one town, and six unincorporated communities. Plaintiff provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

41. State's Attorney of Cook County, Kimberly M. Foxx, is the chief legal officer of the County and is authorized to bring suit on its behalf by and through the assistance of other counsel. State's Attorney Foxx is authorized to bring claims on behalf of the People of the State of Illinois pursuant to 815 ILCS 505/7 and other provisions of the Illinois Consumer Fraud Act.

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

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

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

45. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally, in the State of Illinois and in Cook County, including the following:

Table 1. Purdue Opioids

Drug Name	**Chemical Name**	**Schedule**[27]
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Byprenorpine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

[27] 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.

46. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

47. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the Unites States $635 million – at the time, one of the largest settlements with a drug company for marketing misconduct. Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, which required the company, inter alia, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement.

48. Abbott Laboratories, Inc. is a domestic BCA organized under the laws of Illinois. Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois, and Abbott Laboratories, Inc. is a Illinois corporation with its principal place of business in Abbott Park, Illinois (collectively, "Abbott").

49. Abbott was primarily engaged in the promotion, and distribution of opioids nationally, in the State of Illinois, and in Cook County, due to a co-promotional agreement with Defendant Purdue. Pursuant to that agreement, beginning in 1996, Abbott began actively promoting, marketing and distributing Purdue's opioid products.

50. Abbott, as part of the co-promotional agreement, helped make OxyContin into the largest-selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received 25 to 30 percent of all net sales for prescriptions written by doctors its sales force called on.

51. In 2012, Abbott spun off the company's branded drug business, naming the new company AbbVie, Inc.

52. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Whales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

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

54. 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 Cook County, including the following:

Table 2. Cephalon Opioids

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

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

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

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

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

59. 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.

60. 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.

61. 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.

62. 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 Cook County, including the following:

Table 3. Janssen Opioids

Drug Name	**Chemical Name**	**Schedule**
Duragesic	Fentanyl	Schedule II
Nucynta[28]	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

63. 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.

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

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

65. 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.

66. EHS and EPU (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and in Cook County, including the following:

Table 4. Endo Opioids

Drug Name	**Chemical Name**	**Schedule**
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II

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

68. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on postmarketing data in reaching its conclusion based on the concern that the benefits of the drug may no longer outweigh its risk of abuse.[29]

[29] FDA requests removal of OPANA ER for risks related to abuse. Available at: https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm (accessed August 17, 2017).

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

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

71. Lynn Webster, M.D., is an individual residing in Utah. Dr. Webster was instrumental in promoting opioids for sale and distribution nationally and in Cook County.

FACTS RELEVANT TO ALL CAUSES OF ACTION

A. The Pain-Relieving and Addictive Properties of Opioids

72. "Opiates" are alkaloids derived from the opium poppy, including opium, heroin, morphine, and codeine. "Opioids" are synthetic or partly-synthetic drugs that are manufactured to work in a similar way to opiates. Opioids act like opiates when taken for pain because they have similar molecules. The products manufactured by Defendants are opioids. The term "opioids" is now commonly used for both natural and synthetic versions, and that term is used herein to refer to both.

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

74. 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.

75. 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.

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

77. In 1986, Dr. Russell 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]

[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).

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

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

79. 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]

80. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms

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[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).
[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)).

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.

81. 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.

82. The effects of 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.

83. 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.

84. 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

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

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.

85. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[37]

86. 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

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

88. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if

[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).

[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 August 18, 2017).

any, efficacy for back pain and that evidence did not allow judgments regarding long-term use.

89. 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]

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

91. While opioids may work acceptably well for a while, when they are used on a long term basis, function generally declines, as does general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.[39]

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

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[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).

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

93. 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, rebound headaches, and reported a lower quality of life than patients taking other medications.

C. Defendants' Scheme to Change Prescriber Habits and Public Perception

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

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

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

97. 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.

98. 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, Defendants instead sought to distort medical and public perception of existing scientific data.

99. As explained more fully herein and illustrated in Exhibit A, Defendants, collectively and individually, poured vast sums of money into generating articles, creating continuing medical education courses ("CMEs"), and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new, but phony, "consensus" supporting the long-term use of opioids.

D. Defendants Used "Unbranded" Marketing to Evade Regulations and Consumer Protection Laws

100. Drug companies' promotional activity can be branded or unbranded. Unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can evade the extensive regulatory framework governing branded communications.

101. 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. 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 assess accurately the risks and benefits of drugs for their patients.

102. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") places further 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." "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. The term "accompanying" is interpreted broadly to include promotional materials – posters, websites, brochures, books, and the like – disseminated by or on behalf of the manufacturer of the drug. Thus, Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

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

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

105. 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.

106. 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.

107. 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.

108. 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. In addition, and as described herein, Defendants' sales representatives distributed third-party and unbranded marketing material to Defendants' target audience that was deceptive.

109. 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 fraudulently to promote the use of opioids for the treatment of chronic pain.

110. 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.

i. Defendants' KOLs

111. 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.

112. In return for their pro-opioid advocacy, Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. Defendant KOL Dr. Webster has received funding from Endo, Abbott, Purdue, and Cephalon. Defendant KOL Dr. Fine has received funding from Janssen, Cephalon, Endo and Purdue.

113. 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.

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

115. 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.

ii. Defendants' Corruption of Scientific Literature

116. 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.

117. 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.

118. 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.

119. 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.

120. 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 infamously, 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 made it appear that the item reported the results of a peer reviewed study. Endo cited the same item in two CME programs that it sponsored. Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter-to-the-editor, not a study, much less a peer-reviewed study. The letter, reproduced in full below, states that the authors examined their files of hospitalized patients who had received opioids.

121. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor, indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were, for how long. None of these serious

limitations was disclosed when Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

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

123. 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.

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

iii. Defendants' Misuse of Treatment Guidelines

125. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

a. The Federation of State Medical Board

126. 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.

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

128. 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 Cook County.

129. The 2007 publication Responsible Opioid Prescribing was backed largely by drug manufacturers, including Purdue, Abbott, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of Responsible Opioid Prescribing were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medication (CME) activity for prescribers of opioid medications."

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

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

b. American Academy of Pain Medicine/American Pain Society Guidelines

131. 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.[40] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

132. 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 KOL Defendant Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

133. 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

[40] The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997). Available at http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf (as viewed August 18, 2017).

of times in academic literature, were disseminated in Cook County during the relevant time period, and were and are available online.

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

c. Guidelines that Did Not Receive Defendants' Support

135. 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.

136. 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."[41]

[41] 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).

137. 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."[42]

138. 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.[43]

iv. Defendants' Misuse of CMEs

139. 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 CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

140. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation.

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

[43] 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.mirecc.va.gov/docs/visn6/CPG_Management_Opioid_Tx_Chronic_Pain_May10.pdf (accessed August 18, 2017).

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.

141. 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, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

142. 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."[44]

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

144. By sponsoring CME programs put on by Front Groups like APF, AAPM and others, Defendants could expect 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

[44] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).

Defendants measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

v. Defendants' Misuse of Patient Education Materials and Front Groups

145. 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."[45] 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.[46] 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.

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

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

[46] 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).

and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. 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.

d. American Pain Foundation

147. The most prominent 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. Purdue provided $1.7 million in funding during a time when sales of its OxyContin, being co-promoted by Abbott was skyrocketing.

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

149. 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.

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

151. 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.

152. The close 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 supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

153. 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."[47]

e. The American Academy of Pain Medicine

154. 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.

155. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM 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.

[47] American Pain Foundation Website. Available at http://www.painfoundation.org (accessed August 17, 2017).

156. 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, 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."[48]

157. 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.

vi. Defendants' Misuse of Sales Representatives and Physician Relationships

158. Defendants' sales representatives executed carefully crafted marketing tactics, developed by the highest rungs of their corporate leaders, on how to secure audiences with physicians to pitch opioids and how to make sure physicians and their patients reviewed unbranded marketing materials and considered concepts developed in those materials. Defendants' sales representatives also distributed third-party marketing material to Defendants' target audience that was deceptive.

159. While Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Defendants called "detailers" to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and in Cook County. By establishing close relationships with doctors, Defendants were able to disseminate their

[48] *Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine*, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829 (accessed August 18, 2017).

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.

160. 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 Cook County.

161. Defendants devoted massive resources to these direct sales contacts with prescribers. For example, in 2014, the industry collectively spent $168 million on detailing opioids to physicians nationwide. Collectively, Defendants' have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that detailers' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits, and face-to-face detailing has the highest influence on intent to prescribe. The Defendants could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers, whom they targeted for detailing and who responded by prescribing more the Defendants' drugs.

162. Nowhere is the influence of face-to-face detailing more apparent than as revealed in both the execution and success of the 1996 opioid co-promotion agreement between Purdue and Abbott.

163. Abbott was a much larger company than Purdue when the two joined forces in 1996 and entered a co-promotion agreement for Purdue's opioid, OxyContin. Abbott had a sales force entrenched in hospitals and surgical centers with existing

relationships with all the people: anesthesiologists, emergency room doctors, surgeons, and pain management teams. Abbott devoted at least 300 sales reps to OxyContin sales which was approximately the same number of people Purdue initially dedicated to the drug. Purdue had the product to sell.

164. As set forth herein, the highest ranked executives of both Abbott and Purdue provided detailed marketing direction, sales goals, reliance materials, and suggested unbranded marketing materials and concepts to their sales representatives. The match proved wildly lucrative for both companies.

165. With Abbott's help, sales of OxyContin went from $49 million in its first full year on the market to $1.6 billion in 2002. Abbott actively marketed OxyContin from 1996 through 2002 then continued to participate with Purdue through 2006. Over the life of the agreement, Abbott was paid hundreds of millions of dollars.

166. Abbott heavily incentivized its sales staff to push OxyContin, offering $20,000 cash prizes and luxury vacations to top performers. The company used Middle Age Crusade terminology: Sales reps were called "Crusaders" in the "Royal Court of OxyContin," executives referred to in memos as the "Wizard of OxyContin", "Supreme Sovereign of Pain Management" and the "Empress of Analgesia". The head of pain care sales, Jerry Eichorn, was the "King of Pain" and signed memos simply "King."

167. In one particular memo to Sales Reps, two Abbott Reps were received high accolades from "The Kingdom of Abbott Pain Management" for a "particularly outstanding Crusader success story." These representatives successfully gained an audience with an orthopedic surgeon by effectuating a number of strategic steps to interact with the target surgeon:

- Scheduling a luncheon to discuss the OxyContin dosing card and an Anesthesia & Analgesia Abstract referencing oxycodone as an effective analgesic;[49]

[49] Referenced in Abbott's document Ginsberg et al. Conversion from IV PCA morphine to oral controlled release oxycodone tablets [OxyContin] for postoperative pain

- Developing a "sweet strategy" to "capture his attention and develop our relationship [] through junk food…";
- Asking him to switch three patients per week to OxyContin.

168. In this same memo, the "Empress of Analgesia" pushed Sales Reps to hone their focus on 50 key surgeons and anesthesiologists, more specifically to "target those who have the potential to widely prescribe OxyContin and Vicoprofen on a consistent basis each month." The "King of Pain" encouraged sales representatives to use emotion in their sales tactics, and then supplied examples, both based on vague science:

> Did Doctor X have disruptive callbacks from Patient Y today, unhappy with his bread-through pain levels on Percocet? Explain how OxyContin smooth, sustained blood level throughout 12 hours should alleviate this problem by keeping patients comfortable. Is Surgeon A concerned about the euphoria Patient B is experiencing from Vicodin? Tell your doctor that, with its longer half life, OxyContin has fewer such effects.

169. Abbott and Purdue sales representatives wooed doctors with food, gifts, and influence peddling, techniques which netted them both a huge portion of profits from opioid sales in Cook County, in Illinois, and nationwide. The sales forces of Abbott and Purdue worked in tandem, holding regular strategy sessions, alternating meeting locations between Purdue's Connecticut headquarters and Abbott's corporate offices in Illinois.

170. Defendants directed the dissemination of the misstatements described herein to Illinois patients and prescribers through the Front Groups, KOLS, and publications described above, as well as through its substantial sales force in Cook County, in Illinois, and nationwide and through advertisements in prominent medical journals. The deceptive statements distributed through each of these channels reflect a common theme of misrepresenting

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management. International Anesthesia Research Society, 72nd Clinical and Scientific Congrell, Orlando, Florida, March 1998.

E. Defendants Acted in Concert with KOLs and Front Groups in the Creation, Promotion, and Control of Unbranded Marketing.

171. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superiority of opioids to treat chronic pain.

172. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated nationwide, including to Cook County prescribers and patients.

173. One Vehicle for Defendants' marketing collaboration was 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."

174. 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.

175. 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.[50] This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Defendants' marketing efforts. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

i. Defendants' Misrepresentations

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

177. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks.

[50] 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.

Accordingly, Defendants did not disclose to prescribers, patients or the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Rather, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, doctors practicing within Cook County began prescribing opioids long-term to treat chronic pain – something that most never would have considered prior to Defendants' campaign.

178. Drug company marketing materially impacts doctors' prescribing behavior.[51] 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.

179. Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[52] These results are directly due to Defendants' fraudulent marketing campaign.

[51] *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).

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

180. As described in detail below, Defendants:

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

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

182. 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.[53]

ii. Defendants, acting individually and collectively, misrepresented the truth about how opioids lead to addiction.

183. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. Through their well-funded, comprehensive, aggressive marketing efforts, Defendants succeeded in changing the perceptions of many physicians, patients, and health care payors and in getting them to accept that addiction

[53] 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).

rates are low and that addiction is unlikely to develop when opioids are prescribed for pain. That, in turn, directly led to the expected, intended, and foreseeable result that doctors prescribed more opioids to more patients – thereby enriching Defendants.

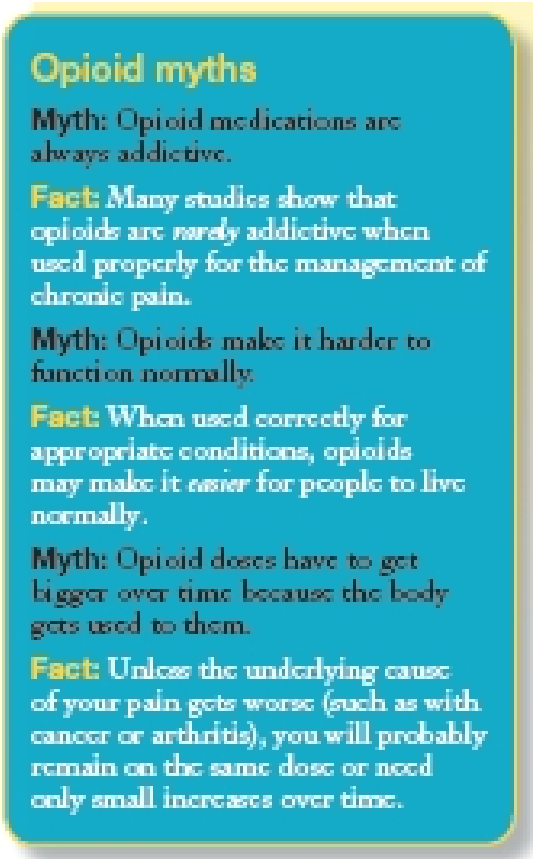
184. Each of the Defendants claimed that the potential for addiction from its drug was relatively small or non-existent, even though there was no scientific evidence to support those claims.

185. For example, Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

186. For another example, Endo sponsored a website, *painknowledge.com*, through APF, which 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 as long as a prescription is given, opioid use will not become problematic.

187. For another example, Endo distributed a patient education pamphlet 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, which is unsupported and untrue.

188. For another example, 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 as a "myth" the fact that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."



Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

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 as long as a prescription is given, opioid use is unlikely to lead to addition, which is untrue.

189. 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.

190. 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.

191. 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.[54] This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

192. For another example, in the 1990s, Purdue amplified the pro-opioid message with promotional videos and featuring 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."[55]

193. 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 relieved their pain using long-term opioid therapy were following the compassionate (and professionally less risky) approach. Defendants claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. The Treatment Options guide funded by Purdue and Cephalon states "[d]espite the great benefits of opioids, they

[54] In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.

[55] Excerpts from one such video, including the statement quoted here, may be viewed at http://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (accessed August 18, 2017).

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."[56]

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

iii. Defendants, acting individually and collectively, misrepresented that opioids improve function

195. 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.

196. Although opioids may initially improve patients' function by providing pain relief in the short term, there exist no controlled studies of the use of opioids beyond 12 weeks and no evidence that opioids improve patients' function in the long-term. Indeed, research such as a 2008 study in the journal *Spine* has shown that pain sufferers

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

prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[57] 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.

197. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."[58]

198. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007), sponsored by drug companies including Cephalon, Endo, Purdue, and Abbott, supported by APF and AAPM, and written by Dr. Fishman and with Dr. Fine on the Board of Advisors, taught that relief of pain itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."[59]

199. 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 available online.

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

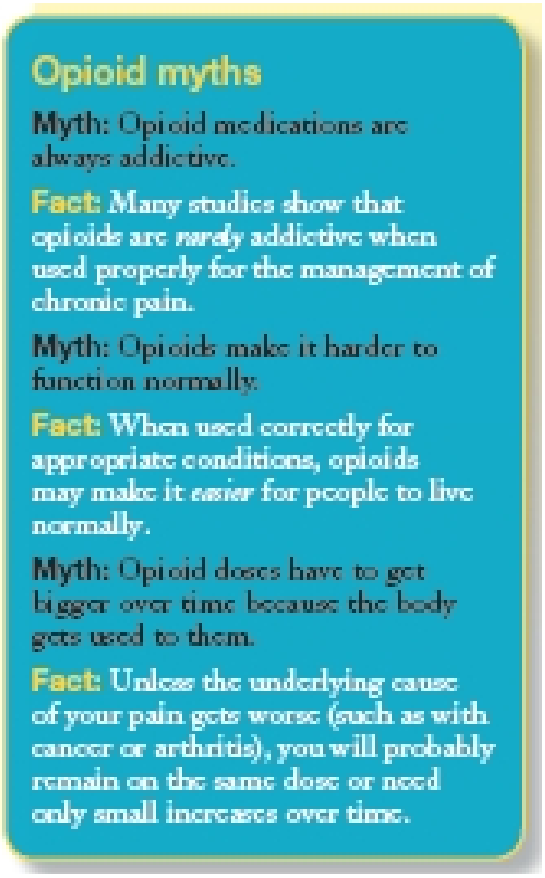
[58] Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, *King Pharmaceuticals*, Re: NDA 21-260 (March 24, 2008).

[59] *Responsible Opioid Prescribing*, (available at https://archive.org/stream/279187-responsible-opioid-prescribing-info/279187-responsible-opioid-prescribing-info_djvu.txt (accessed August 31, 2017).

200. Endo sponsored a website, *painknowledge.com*, through the APF, 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.

201. 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.

202. 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



Opioid myths

Myth: Opioid medications are always addictive.

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Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

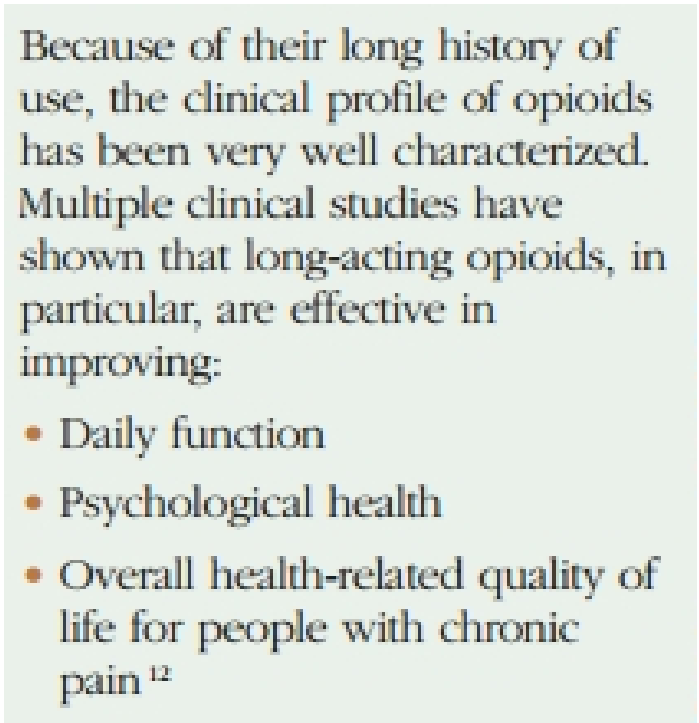
Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

structure implies authoritative support for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.

203. 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.

204. 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 (i) noted the absence of long-term studies and (ii) actually stated, "For functional outcomes, the other analgesics were significantly more effective than were opioids."

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

iv. Defendants, acting individually and collectively, misrepresented that addiction risk can be effectively managed

206. Defendants each continue to maintain to this day that most patients safely can take opioids long-term for chronic pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, Defendants have come to admit 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 say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

207. 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 doctors can depend on the screening tools currently available to materially limit the risk of addiction. Even if the tools are effective, they may not always be applied correctly, and are subject to manipulation by patients. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through screening can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

208. 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."[60] 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 are not proven to work in the real world, even when well meaning, but doctors were misled to employ them.[61]

209. 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

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

[61] 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).

by Defendants to market their drugs, that, of the more than half a million prescribers of opioids during that time period, only 385 were identified as pain specialists.[62]

210. In materials they produced, sponsored, or controlled, 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 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.

211. 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."

212. 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.

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

213. 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."

v. Defendants, acting individually and collectively, misled physicians, patients, and payors through the use of misleading pseudowords like "pseudoaddiction."

214. Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe even 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 Dr. Portenoy. 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.

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

216. Cephalon, Endo, Purdue and Abbott sponsored the Federation of State Medical Boards' Responsible Opioid Prescribing (2007) written by Dr. Fishman and with Dr. Fine on the Board of Advisors, 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."

217. 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."[63]

218. 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 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."

vi. Defendants, acting individually and collectively, claimed withdrawal is simply managed.

219. 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 fail 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 the drugs.

220. In materials Defendants produced, sponsored, and/or controlled, Defendants made misrepresentations to persuade doctors and patients that withdrawal

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

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.

221. 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.[64]

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

vii. Defendants, acting individually and collectively, misrepresented that increased doses pose no significant additional risks.

223. 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.

224. 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.

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

225. 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.[65]

226. 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.

227. 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.

228. Endo distributed a patient education pamphlet 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."

229. 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.

[65] 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).

230. 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 taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

viii. Defendants, acting individually and collectively, deceptively omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

231. 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.

232. 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;)"[66] hormonal dysfunction;[67] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[68] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth); and potentially fatal interactions with alcohol or benzodiazepines (which are

[66] 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).

[67] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001).

[68] See 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).

used to treat post-traumatic stress disorder and anxiety, which often accompany chronic pain symptoms.[69]

233. 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.[70] *Treatment Options* also warned that risks of NSAIDS increase if "taken for more than a period of months," with no corresponding warning about opioids.

234. 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.

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

236. 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

[69] 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).

[70] 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).

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.[71]

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

237. 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.

238. 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.

239. 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

[71] 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).

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.

x. Defendants Fraudulently Concealed their Misrepresentations

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

241. 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.

242. 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.

243. 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.

244. 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.

245. 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.

246. 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.

xi. Defendants Entered into and Engaged in a Civil Conspiracy

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

248. Defendants agreed among 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.

249. This network is interconnected and interrelated, as illustrated 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.

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

FIRST CAUSE OF ACTION
CONSUMER FRAUD – DECEPTIVE PRACTICES
VIOLATIONS OF 815 ILCS 505/1, *ET SEQ*.
(AGAINST ALL DEFENDANTS)

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

252. 815 ILCS 505/1, *et seq*. ("Illinois Consumer Fraud Act" or "ICFA") makes it unlawful for a person or business to use "unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with the intent that others rely upon the concealment, suppression or omission of such material fact" in the conduct of any trade or commerce." 815 ILCS 505/2. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2, also makes unlawful "the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act."

253. Defendants have engaged in unlawful and deceptive business practices in violation of ICFA as set forth above.

254. Defendants' practices as described herein are deceptive business practices that violate ICFA because the practices were and are intended to deceive consumers and occurred and continue to occur in the course of conduct involving trade and commerce in Cook County and throughout Illinois.

255. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and/or by aiding and abetting third parties, violated ICFA by making and disseminating untrue, false, and misleading statements to Illinois prescribers and consumers to promote the sale and use of opioids to treat chronic pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated to Illinois prescribers and consumers in order to promote the sale and use of opioids to treat chronic pain. These untrue, false, and misleading statements included, but were not limited to:

a. misrepresenting the truth about how opioids lead to addiction;

b. misrepresenting that opioids improve function;

c. misrepresenting that addiction risk can be managed;

d. misleading doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"

e. falsely claiming that withdrawal is simply managed;

f. misrepresenting that increased doses pose no significant additional risks;

g. falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

256. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and by aiding and abetting third parties, also violated ICFA by making statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic pain. Defendants and their third-party allies repeatedly failed to disclose or minimized material facts about the risks of opioids, including the risk of

addiction, and their risks compared to alternative treatments. Such material omissions were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opioids untrue, false, and misleading, creating a misleading impression of the risks, benefits, and superiority of opioids for treatment of chronic pain.

257. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and by aiding and abetting third parties, made and disseminated the foregoing untrue, false and misleading statements, and material omissions, through an array of marketing channels, including but not limited to: in-person and other forms of detailing; speaker events, including meals, conferences, and teleconferences; CMEs; studies, and journal articles and supplements; advertisements; and brochures and other patient education materials.

258. Defendants knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions statements to be made or disseminated, that they were untrue, false, or misleading and therefore likely to deceive the public. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks, benefits, and superiority of opioids.

259. In sum, Defendants: (a) directly engaged in untrue, false, and misleading marketing; (b) disseminated the untrue, false, and misleading marketing through third parties; and (c) aided and abetted the untrue, false, and misleading marketing third parties.

260. All of this conduct, separately and collectively, was intended to deceive Illinois consumers who used or paid for opioids for chronic pain; Illinois physicians who prescribed opioids to consumers to treat chronic pain; and Illinois payors, including the County, who purchased, or covered the purchase of, opioids for chronic pain. As a direct result of the foregoing acts and practices, the Defendants have received, or will receive,

income, profits, and other benefits, which they would not have received if they had not engaged in the violations of ICFA as described in this Complaint.

261. By reason of the foregoing, the People of Illinois and the County were injured in that Defendants' unbranded marketing of opioids for chronic pain caused the doctors to prescribe and the People of Illinois and Cook County to pay for long-term opioid treatment using opioids manufactured or distributed by Defendants as well as other drug makers. Defendants caused and are responsible for those costs and claims.

262. In addition, 815 ILCS 505/7 specifically allows the State's Attorney of Cook County to bring this claim for a penalty for each violation by the Defendants.

WHEREFORE, Plaintiffs, the People of Illinois and Cook County, respectfully requests that this Court enter an order (a) awarding judgment in their favor and against Defendants on Count One of the Complaint; (b) awarding Plaintiffs their actual or compensatory damages; (b) compelling Defendants to pay restitution of any money acquired as a result of Defendants' consumer fraud and deceptive practices; (c) compelling Defendants to pay civil penalties up to $50,000 per violation pursuant to 815 ILCS 505/7(b) for each violations; (d) compelling Defendants to disgorge their ill-gotten profits; (e) compelling Defendants to pay the costs of the suit, including attorneys' fees; and (f) awarding the Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

SECOND CAUSE OF ACTION
UNIFORM DECEPTIVE ACTS AND PRACTICES VIOLATION
VIOLATIONS OF 815 ILCS 510/1, *ET SEQ*.
(AGAINST ALL DEFENDANTS)

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

264. 815 ILCS 510/1 *et seq.* ("Uniform Deceptive Trade Practices Act" or "UDAP") makes it unlawful for a person or business to represent that goods have a

quality, use, benefit or characteristic they do not possess or engages in any conduct which may cause a likelihood of confusion or misunderstanding.

265. At all times relevant to this Complaint, the Defendants, directly, through their control of third parties, and/or by aiding and abetting third parties, violated the Uniform Deceptive Trade Practices Act by engaging in unfair acts or practices to promote the sale and use of opioids to treat chronic pain. These acts or practices are unfair in that they offend public policy; are immoral, unethical, oppressive, or unscrupulous; and have resulted in substantial injury to Illinois consumers, including Cook County.

266. The Defendants' unfair acts or practices include, but are not limited to:

a. Targeting a vulnerable population—the elderly—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death;

b. Targeting a vulnerable population—veterans—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, overdose, and self-inflicted or accidental injury;

c. Deliberately using unbranded marketing to evade FDA oversight and rules prohibiting deceptive marketing.

267. The Defendants engaged in these practices both directly and through the KOLs and Front Groups that they controlled and/or which they aided and abetted. The Defendants were aware of the unfair conduct of the KOLs and Front Groups, and yet the Defendants provided them substantial assistance and encouragement by helping them engage in the unfair practices. The Defendants also substantially encouraged the unfair practices by providing the Front Groups and KOLs with funding and technical support for the shared purpose of issuing unfair, pro-opioid messaging.

268. The Defendants' promotional practices as described above offend deep-seated public policies. As the Illinois legislature has decreed, "drug addiction [is] among

the most serious health problem [] facing the people of the State of Illinois."[72] Nevertheless, by engaging in the conduct alleged above, the Defendants actively worked to conceal the risk of addiction related to opioids from Illinois patients and prescribers in the hopes of selling greater quantities of their dangerous drugs. The Defendants also worked to undermine public policy, enshrined by regulations contained in state and federal law, that is aimed at ensuring honest marketing and safe and appropriate use of pharmaceutical drugs.

269. The Defendants' conduct also was oppressive to both patients and prescribers. Patients are laypersons who put their trust in physicians to appropriately convey and balance the risks and benefits of various treatment options. Physicians, in turn, are inclined to trust the advice of KOLs, Front Groups, and other seemingly independent sources of objective medical information. By engaging in the conduct described above, the Defendants co-opted the sources reasonable physicians relied upon to convince those physicians that the risks related to opioids were minimal, that the benefits were substantial, and—as a result—that opioids were medically necessary to treat their patients' chronic pain. The Defendants deliberately targeted non-specialist physicians and non-physician prescribers, who lacked the time and expertise to evaluate their deceptive claims. This is even more true of the patients who were both the subject and object of the Defendants' marketing; patients have little ability to independently evaluate the medical necessity of the treatments they are prescribed and rely on the judgment of their physicians instead—the same judgment that was compromised by the Defendants' unlawful conduct.

270. Finally, the Defendants' conduct has caused substantial, indeed grievous, injury to Illinois consumers, including Cook County. The staggering rates of opioid use, abuse, and addiction, in the County alone, resulting from the Defendants' marketing

[72] 745 ILCS 35/2.

efforts have caused substantial injury to the People of Illinois and the County, including, but not limited to, costs incurred, and continuing to be incurred by the People of Illinois and the County. These costs stem from opioid use by Illinois consumers, the costs of which are passed on to the People of Illinois and the County, such as:

a. A substantial number of adults have used opioids, with the vast majority of the use stemming from prescribing for chronic pain conditions.

b. A substantial number of Illinois residents prescribed opioids long-term for chronic pain have experienced the life-upending effects of addiction, abuse, misuse, overdose and death. For those who can stop taking narcotic opioids, there are years of struggling with the pull of the drugs and the fear of relapse (and often relapse itself), counseling sessions, or lining up each morning for daily maintenance drugs. And those who cannot overcome the need for opioids must deal with the compulsive use of and need for opioids, the haziness when they are on the drugs, and the nearly constant struggle to maintain their supplies of the drugs, whatever the cost. Both groups face a dramatically heightened risk of serious injury to death and sometimes an unrecoverable roll on their health, work, and family.

c. Elderly Illinoisans and Illinois veterans are particularly vulnerable to serious adverse outcomes, including overdose, injury, and death;

d. Illinoisans who have never taken opioids also have also been injured. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids. Infants born to mothers who abuse opioids have suffered neonatal abstinence syndrome.

e. Illinois consumers have incurred health care costs due to the prescription of opioids for chronic pain and the treatment of opioids' adverse effects, including addiction and overdose.

f. The Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. The Defendants' scheme created both ends of a new

secondary market for opioids— providing both the supply of narcotics to sell and the demand of addicts to buy them.

g. This demand also has created additional illicit markets in other opiates, particularly heroin. Patients addicted to opioids frequently migrate to lower-cost heroin, with the serious personal costs that accompany their use of unlawful drugs.

h. All of this has caused substantial injuries to consumers—in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken lives, families, and homes.

271. The profound injuries to Illinois consumers, including the People of Illinois and the County, are substantial. No public policy justifies the Defendants' conduct in overstating the benefits, denying or downplaying the risks, and misrepresenting the superiority of opioids for chronic pain, which deprived Illinois patients and doctors of the honest and complete information they need to make informed choices about their treatment. In light of this campaign of misinformation (and especially given the addictive nature of these drugs), neither Illinois consumers nor the County could reasonably have avoided their injuries.

272. The People of Illinois and the County were injured as a result of Defendants' unfair and deceptive acts and practices targeted toward Illinois consumers. At a minimum, the People of Illinois and the County seek to enjoin the Defendants from continuing their unfair and deceptive acts and practices.

WHEREFORE, Plaintiffs, the People of the State of Illinois and Cook County, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Two of the Complaint; (b) enjoin Defendants from further unfair and deceptive acts and practices; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

THIRD CAUSE OF ACTION
CIVIL CONSPIRACY

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

274. As set forth herein and in Exhibit A, Defendants conspired with various KOLs and Front Groups to commit unlawful acts or lawful acts in an unlawful manner. Defendants knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote the use of opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants enlisted various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase opioid sales, and Defendants—along with the Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

275. By engaging in the conduct described in this Complaint, Defendants agreed with Front Groups that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with one another and Front Groups, provided support for Front Group's deceptive statements promoting opioids and Front Groups used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Defendants' drug sales, as well as other opioid makers' sales. The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit Wounds* (Purdue and APF),[73] *Responsible Opioid Prescribing* (Purdue, Cephalon, Endo, Abbott, APF, AAPM, and FSMB), and a

[73] Purdue's collaboration with APF through APF's "Corporate Roundtable" and Purdue and APF's active collaboration in running PCF constitute additional evidence of the conspiracy between Purdue and APF to deceptively promote opioids.

CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined in greater detail herein. They are products of these conspiracies, and the collaboration between Defendants and each of these entities in creating and disseminating these publications, CMEs, and websites is further evidence of each conspiracy's existence.

276. Each of the participants to the conspiracies outlined herein and in Exhibit A was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to Illinois patients and prescribers in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

277. As outlined in greater detail herein and in Exhibit A, opioid makers Cephalon, Endo, Janssen, along with Defendants Purdue and Defendant KOLs played an active role in determining the substance of the misleading messages issued by Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was an unrelenting stream of misleading information about the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers. Defendants exercised direct editorial control over most of these statements. However, even if Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

278. Defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

a. violating, aiding and abetting in the violation, or causing the violation of the Illinois Consumer Fraud Act;

b. violating, aiding and abetting in the violation, or causing the violation of the Uniform Deceptive Practices Act;

c. violating, aiding and abetting in the violation, or causing the violation of 720 ILCS § 5/17-10.5;

d. perpetrating a public nuisance; and

e. committing common law unjust enrichment.

279. By reason of the foregoing, the County was injured and continues to be injured in that Defendants' ongoing concerted actions in marketing opioids caused doctors and other health care providers to prescribe and the County to pay for long-term opioid treatment using opioids manufactured by Defendants or by other drug makers, Defendant caused and are responsible for those costs and claims. In addition, the County has suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

WHEREFORE, Plaintiff, Cook County, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Three of the Complaint; (b) compelling these Defendants to pay Cook County's direct and consequential damages; and (c) awarding Cook County such other, further, and different relief as this Honorable Court may deem just.

FOURTH CAUSE OF ACTION
INSURANCE FRAUD
VIOLATION OF 720 ILCS 5/17-10.5
(AGAINST ALL DEFENDANTS)

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

281. 720 ILCS § 5/17-10.5(a)(1) provides in pertinent part:

> A person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.

282. 720 ILCS § 5/17-10.5(e)(1) provides in pertinent part:

> Civil damages for insurance fraud. A person who knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of any insurance company by the making of a false claim or by causing a false claim to be made on a policy of insurance issued by an insurance company, or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property, shall be civilly liable to the insurance company or self-insured entity that paid the claim or against whom the claim was made or to the subrogee of that insurance company or self-insured entity in an amount equal to either 3 times the value of the property wrongfully obtained or, if no property was wrongfully obtained twice the value of the property attempted to be obtained, whichever amount is greater, plus reasonable attorney's fees.

283. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and by acting in concert with third parties: (a) knowingly caused false claims to be made to the County's health plan and workers' compensation program, which are self-insured; and (b) knowingly obtained or caused to be obtained through deception the property of the County in payments for those false claims. Defendants'

scheme caused prescribers to write prescriptions for opioids to treat chronic pain that were presented to the County's health plans and workers' compensation program for payment. Therefore, each claim for reimbursement to the County for chronic opioid therapy is the direct result of Defendants' marketing, which presented to prescribers false information about the risks, benefits, and superiority of opioids for the long-term treatment of pain.

284. Further, the County only covers the cost of services, tests, and prescription drugs that are medically necessary, reasonably required, and prescribed for an FDA-approved use. Doctors, pharmacists, other health care providers, and/or other agents of the health plans and workers' compensation program expressly or impliedly certified to the County that opioids were medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements disseminated by Defendants (or the medical Defendants made the misrepresentations themselves) about the risks, benefits, and superiority of opioids for chronic pain.

285. The misrepresentations were material because if the County had known of the false statements disseminated by Defendants and that doctors, pharmacies, other health care providers, and/or the health plans and workers' compensation program certified and/or determined that opioids were medically necessary and reasonably required based on those false statements, the County would have refused to authorize payment for opioid prescriptions. The County is a self-insured entity and directly covers the cost of prescription drugs and other medical services for the County employees and retirees.

286. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made false claims with the intent to induce the County to approve and pay such false and fraudulent claims.

287. By virtue of the above-described acts, Defendants acted in concert with third party Front Groups and KOLs to make misleading statements about the risks,

benefits, and superiority of opioids to treat chronic pain. Defendants were aware of the misleading nature of the misstatements and material omissions made by KOLs and Front Groups, and yet Defendants provided them substantial assistance and encouragement by helping them develop, refine and promote these misstatements and material omissions and distributing them to a broader audience. Defendants also substantially encouraged the dissemination of these misstatements and material omissions by providing the Front Groups and KOLs with funding and technical support for the shared purpose of issuing misleading, pro-opioid messaging. Defendants knew or should have known that these marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain and would result in the submission of false insurance claims for opioid prescriptions written to treat chronic pain.

288. By reason of the foregoing, the County has been injured in that Defendants' unbranded marketing cause the doctors to prescribe and the County to pay for long-term opioid treatment using opioids manufactured or distributed by Defendants, and Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of 720 ILCS § 5/17-10.5(a)(1) as described in this Complaint.. Defendants caused and responsible for those costs and claims, as well as their enrichment.

WHEREFORE, Plaintiff, Cook County, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Four of the Complaint; (b) compelling Defendants to pay three times any money acquired as a result of Defendants' fraud; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding Cook County such other, further, and different relief as this Honorable Court may deem just.

FIFTH CAUSE OF ACTION
PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)

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

290. Defendants' conduct constitutes a public nuisance.

291. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of persons in the County by their untrue, false, and mispleading promotion, and marketing of opioids for use by residents of the County.

292. Defendants' marketing conduct and subsequent sale of its opioid products is not only unlawful, but has also resulted in substantial and unreasonable interference with the public health, and the public's enjoyment of its right that not to be defrauded or negligently injured.

293. Defendants' conduct is not insubstantial or fleeting. Indeed, Defendants' unlawful conduct has so severely impacted public health on every geographic and demographic level that the public nuisance perpetrated by Defendants' conduct is commonly referred to as a "crisis" or an "epidemic." It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

294. By reason of the foregoing, the County has been injured and continues to be injured in that it has paid and continues to pay for long-term opioid treatment using opioids manufactured or distributed by Defendants or by other drug makers. The County has suffered additional damages and continues to suffer damage for the additional costs of providing and using opioids long-term to treat chronic pain.

295. WHEREFORE, Plaintiff, Cook County, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Five of the Complaint; (b) enjoining Defendants' to abate the public nuisance; (b) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (c) awarding Cook County such other, further, and different relief as this Honorable Court may deem just.

SIXTH CAUSE OF ACTION
UNJUST ENRICHMENT
VIOLATIONS OF THE COMMON LAW PROHIBITION ON UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

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

297. Defendants have unjustly retained a benefit to Cook County's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

298. By illegally and deceptively promoting opioids to treat chronic pain, directly, through their control of third parties, and by acting in concert with third parties, Defendants have unjustly enriched themselves at Cook County's expense. Cook County has made payments for opioid prescriptions, and Defendants benefited from those payments. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the County lacks a remedy provided by law.

299. In addition, and by reason of the foregoing, the County was injured and continues to be injured in that Defendants' ongoing concerted actions in illegally and deceptively marketing opioids caused doctors and other health care providers to prescribe and the County to pay for long-term opioid treatment using opioids manufactured by Defendants or by other drug makers, Defendants caused and are responsible for those costs and claims. The County has suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

WHEREFORE, Plaintiff, Cook County, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Six of the Complaint; (b) compelling Defendants to disgorge all unjust enrichment to Cook County; and (c) awarding Cook County such other, further, and different relief as this Honorable Court may deem just.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand judgment against Defendants, jointly and severally, awarding Plaintiffs:

1. compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages;

2. treble damages, penalties, and costs pursuant to Consumer Fraud – Deceptive Practices, violation of 815 ILCS 505/1, *et seq*;

3. treble damages, penalties, and costs pursuant to Uniform Deceptive Acts and Practices, violation of 815 ILCS 510/1, *et seq*;

4. treble damages, penalties, and costs pursuant to Insurance Fraud Law 720 ILCS 5/17-10.5;

5. a declaratory judgment requiring Defendants to abate the public health nuisance;

6. punitive damages;

7. interest, costs, and disbursements; and

8. such other and further relief as this Court deems just and proper.

Dated: December 27, 2017

/s/ Peter J. Flowers

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Exhibit A

Relationships between Corporations and Physicians, uses of Front Groups and Selective Deceptive Marketing Materials and Resources