FILED
LORAIN COUNTY
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COURT OF COMMON PLEAS
TOM ORLANDO

IN THE COURT OF COMMON PLEAS
LORAIN COUNTY, OHIO

THE COUNTY OF LORAIN
Lorain County Administration Building
226 Middle Avenue, 4th Floor
Elyria, Ohio 44035

Plaintiff,

v.

PURDUE PHARMA L.P.
c/o The Prentice Hall Corporation
2711 Centerville Road
Wilmington, DE 19808

and

PURDUE PHARMA INC.
c/o The Prentice Hall Corporation
2711 Centerville Road
Wilmington, DE 19808

and

THE PURDUE FREDERICK COMPANY, INC.
c/o The Prentice Hall Corporation
2711 Centerville Road
Wilmington, DE 19808

and

TEVA PHARMACEUTICALS USA, INC.
c/o Corporate Creations Network Inc.
3411 Silverside Road
Wilmington, DE 19810

and

CEPHALON, INC.
c/o Corporate Creations Network Inc.
3411 Silverside Road
Wilmington, DE 19810

CASE NO.:

JUDGE:

17 CV 194035

JUDGE RAYMOND J. EWERS

COMPLAINT FOR DAMAGES

(JURY DEMAND HEREON)

)
and)
)
JOHNSON & JOHNSON)
One Johnson & Johnson Plaza)
New Brunswick, NJ 08933)
)
and)
)
JANSSEN PHARMACEUTICALS, INC.)
116 Pine Street, Suite 320)
Harrisburg, PA 17101)
)
and)
)
ORTHO-MCNEIL-JANSSEN)
PHARMACEUTICALS, INC. N/K/A JANSSEN)
PHARMACEUTICALS, INC.)
116 Pine Street, Suite 320)
Harrisburg, PA 17101)
)
and)
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JANSSEN PHARMACEUTICA, INC. N/K/A)
JANSSEN PHARMACEUTICALS, INC.)
116 Pine Street, Suite 320)
Harrisburg, PA 17101)
)
and)
)
ENDO PHARMACEUTICALS, INC.)
c/o The Corporation Trust Co.)
1209 Orange Street)
Wilmington, DE 19801)
)
and)
)
ALLERGAN PLC F/K/A ACTAVIS PLC)
CT Corporation System)
4400 Easton Commons Way, Suite 125)
Columbus, Ohio 43215)
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and)
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ACTAVIS, INC. F/K/A WATSON)
PHARMACEUTICALS, INC.)
Corporate Creations Network, Inc.)
119 E. Court Street)
Cincinnati, Ohio 45202)
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and)
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WATSON LABORATORIES, INC.)
Corporate Creations Network Inc.)
119 E. Court Street)
Cincinnati, OH 45202)
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and)
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ACTAVIS LLC)
Corporate Creations Network Inc.)
119 E. Court Street)
Cincinnati, OH 45202)
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and)
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ACTAVIS PHARMA, INC. F/K/A WATSON)
PHARMA, INC.)
Corporate Creations Network Inc.)
119 E. Court Street)
Cincinnati, OH 45202)
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and)
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ENDO HEALTH SOLUTIONS INC.)
c/o The Corporation Trust Co.)
1209 Orange Street)
Wilmington, DE 19801)
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and)
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INSYS THERAPEUTICS, INC.)
1333 S. Spectrum Blvd. #100)
Chandler, Arizona 85286)
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and)
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MCKESSON CORPORATION)
50 West Broad Street, Suite 1330)
Columbus, Ohio 43215)

)
and)
)
CARDINAL HEALTH, INC.)
7000 Cardinal Place)
Dublin, Ohio 43017)
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and)
)
AMERISOURCEBERGEN DRUG)
CORPORATION)
c/o The Corporation Trust Company)
Cleveland, Ohio 44114)
)
and)
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MIAMI-LUKEN, INC.)
265 Pioneer Blvd.)
Springboro, OH 45066)
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and)
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RUSSELL PORTENOY)
39 Broadway, 1st Floor)
New York, NY 10006)
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and)
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PERRY FINE)
615 Arapeen Way, Suite 155)
Salt Lake County, UT 84132)
)
and)
)
SCOTT FISHMAN)
2221 Stockton Blvd.)
Sacramento, CA 95817)
)
and)
)
LYNN WEBSTER)
PRA Health Sciences)
3838 S 700 E #202)
Salt Lake County, UT 84106)

Defendants.

Plaintiff, the County of Lorain, Ohio ("Plaintiff," "County," or "County of Lorain"), by and through its attorney, for its Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma Inc.; the Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan plc f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. and Insys Therapeutics, Inc. (collectively, "Manufacturers" or "Defendants"); McKesson Corporation, Cardinal Health Inc., Amerisource Drug Corporation, Miami-Luken, Inc. (Collectively, "Distributor Defendants" or "Defendants") Russell Portenoy; Perry Fine; Scott Fishman; and Lynn Webster; (collectively, "Physicians" or "Defendants") alleges as follows:

INTRODUCTION

1. This case is about one thing: corporate greed. Defendants put their desire for profits above the health and well-being of the County of Lorain consumers at the cost of Plaintiff.

2. The County of Lorain spends millions of dollars each year to provide and pay for health care, services, pharmaceutical care and other necessary services and programs on behalf of residents of its County whom are indigent or otherwise eligible for services, including payments through services such as Medicaid for prescription opioid painkillers ("opioids") which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.

3. The County of Lorain also provides a wide range of other services to its residents, including law enforcement, services for families and children, and public assistance.

4. In recent years, the County of Lorain has been forced to expend exorbitant amounts of money, described further below, due to what is commonly referred to as the "opioid epidemic" and as a direct result of the actions of Defendants.

5. Plaintiff is the ninth largest County in the state of Ohio, and employs thousands of people. Plaintiff is also responsible for partially funding a medical insurance plan for its employees.

6. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. Yet they also knew–and had known for years–that opioids were addictive and subject to abuse, particularly when used long-term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as "chronic pain"), and should not be used except as a last-resort.

7. Defendants further knew–and had known for years–that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of significant side effects and addiction.[1, 2]

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

9. Indeed, the U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[3]

10. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, are narcotics. They are derived from or

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[1] *See, e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994).

[2] The authoritative *Diagnostic and Statistical Manual of Mental Disorders*, (5th ed. 2013) ("DSM-V") classifies addiction as a spectrum of "substance use disorders" that ranges from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on the substance use disorder continuum. Throughout this Complaint, "addiction" refers to this range of substance use disorders.

[3] 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).

possess properties similar to opium and heroin, which is why they are regulated as controlled substances.[4] Like heroin, prescription opioids work by binding to receptors on the spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and, ultimately, death.

11. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea change in the medical and public perception that would permit the use of opioids not just for acute and palliative care, but also for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches.

12. Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the late 1990s, deepened around 2006, and continues to the present, set out to, and did, reverse the popular and medical understanding of opioids. Chronic opioid therapy—the prescribing of opioids to treat chronic pain long-term—is now commonplace.

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[4] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. 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. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription from a doctor, which may not be refilled, and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin), fentanyl (Duragesic, Actiq, Fentora), methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone). 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. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription, which may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs, like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II. *See* 21 C.F.R. § 1308.

13. To accomplish this reversal, Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids used long-term to treat chronic pain (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids (c) recruiting prescribing physicians as paid speakers as a means of both securing those physicians' future "brand loyalty" and extending their reach to the physicians' peers; (d) funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("KOLs"), not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs ("CMEs") that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and (e) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups") that developed educational materials and treatment guidelines that were then distributed by Defendants, which urged doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

14. These efforts, executed, developed, supported, and directed by Defendants, were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors and patients that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be used safely by most patients. Defendants and the third parties whom they recruited and supported, all profited handsomely through their dissemination of these deceptions. KOLs and Front Groups saw their stature in the medical community elevated dramatically due to Defendants' funding, and Defendants saw an equally dramatic rise in their revenues.

15. Working individually, with, and through these Front Groups and KOLs, Defendants pioneered a new and far broader market for their potent and highly addictive drugs— the chronic pain market. Defendants persuaded doctors and patients that what they had long understood—that opioids are addictive drugs and unsafe in most circumstances for long-term use— was untrue, and to the contrary, that the compassionate treatment of pain *required* opioids. Ignoring the limitations and cautions in their own drugs' labels, Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured their serious risks and adverse outcomes, including the risk of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There was, and is, no reliable scientific evidence to support Defendants' marketing claims, and there was, and is, a wealth of scientific evidence that these claims are false. Defendants also deceptively and unfairly marketed the drugs for indications and benefits that were outside of the drugs' labels and not supported by substantial evidence.

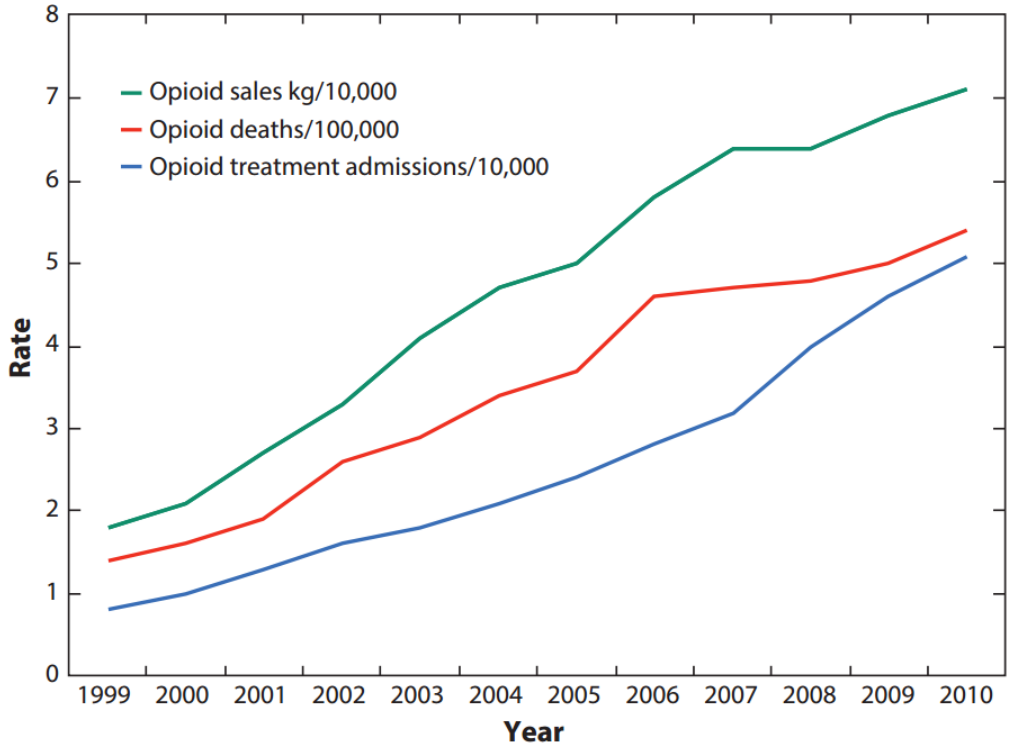
16. Even Defendants' KOLs initially were very cautious about whether opioids were appropriate to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers, and physicians who have sounded the alarm on the overprescribing of opioids to treat chronic pain, Defendants continue to disseminate their misleading and unfair marketing claims to this day.

17. Defendants' efforts were wildly successful. The United States is now awash in opioids. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers— enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits in

2010 resulted in the prescription of an opioid, nearly double the rate in 2000. Opioids—once a niche drug—are now the most prescribed class of drugs—more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply. Together, opioids generated $8 billion in revenue for drug companies in 2012.

18. It was Defendants' marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

19. There is a direct correlation between the sales of opioids and deaths and hospitalizations caused by opioids[5]:

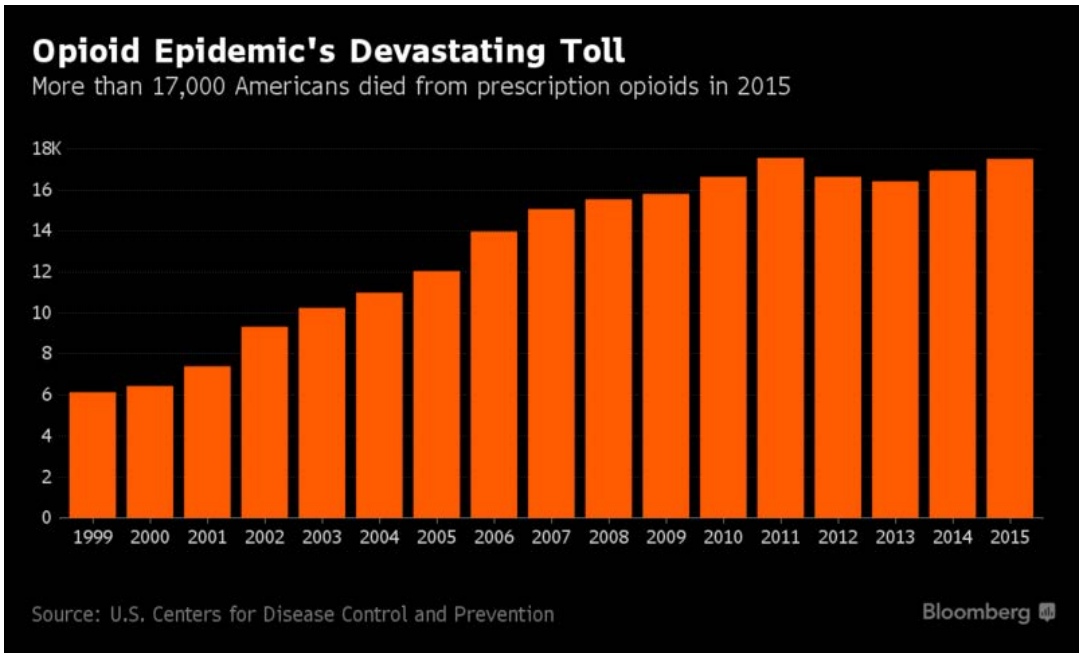


Source: Annual Review of Public Health

[5] *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction.*, Annu. Rev. Public Health 2015, accessed at http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957

20. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic." [6] According to the CDC, prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. One Defendant's own 2010 internal data shows that it knew that the use of prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008, and that the trend of opioid poisonings was increasing from 1999-2008. For every death, more than 30 individuals are treated in emergency rooms.

21. As a direct result of the opioid and eventual heroin epidemic more than 17,000 Americans died from prescription opioids in 2015 and the number continues to steadily grow, specifically in places such as the County of Lorain, Ohio. [7]



22. According to the Ohio Department of Health, in 2007 unintentional drug poisoning became the leading cause of injury death in Ohio, surpassing motor vehicle accidents for the first time

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

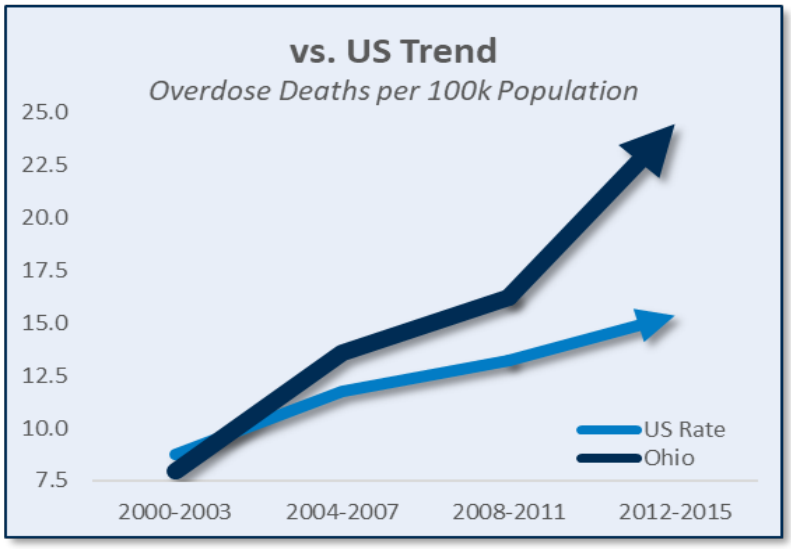
[7] https://www.bloomberg.com/news/articles/2017-06-28/life-after-opioids-drugmakers-scramble-to-concoct-alternatives

in history.[8] From 2000 to 2015, Ohio's death rate due to unintentional drug poisonings increased 642 percent, which was "drive largely by opioid related overdoses"[9]

23. In 2014, more people died of opioid overdoses in Ohio than any other state in the Country. [10]

24. In 2000, there were 411 unintentional drug overdose deaths in Ohio. By 2015, this number grew to 3,050.[11]

25. The rate of drug overdose deaths in Ohio have continued to rise at a rate that far exceeds the United States as a whole:[12]



26. Lorain County has seen a significant spikes in overdose deaths due to opioids. In 2012, there were a total of 127 accidental overdose deaths in Lorain County, with 83% associated with opiate use.[13] In 2013, that number jumped over 11%.

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[8] https://www.odh.ohio.gov/health/vipp/drug/dpoison.aspx (accessed on May 30th, 2017)
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2015 on CDC WONDER Online Database, released December, 2016. Data are from the Multiple Cause of Death Files, 1999-2015, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/ucd-icd10.html on Jul 26, 2017. ICD-10 Codes: X40–X44, X60–X64, X85, and Y10–Y14

27. The number of unintentional drug overdose totals in Lorain County have skyrocketed since 2004[14]:

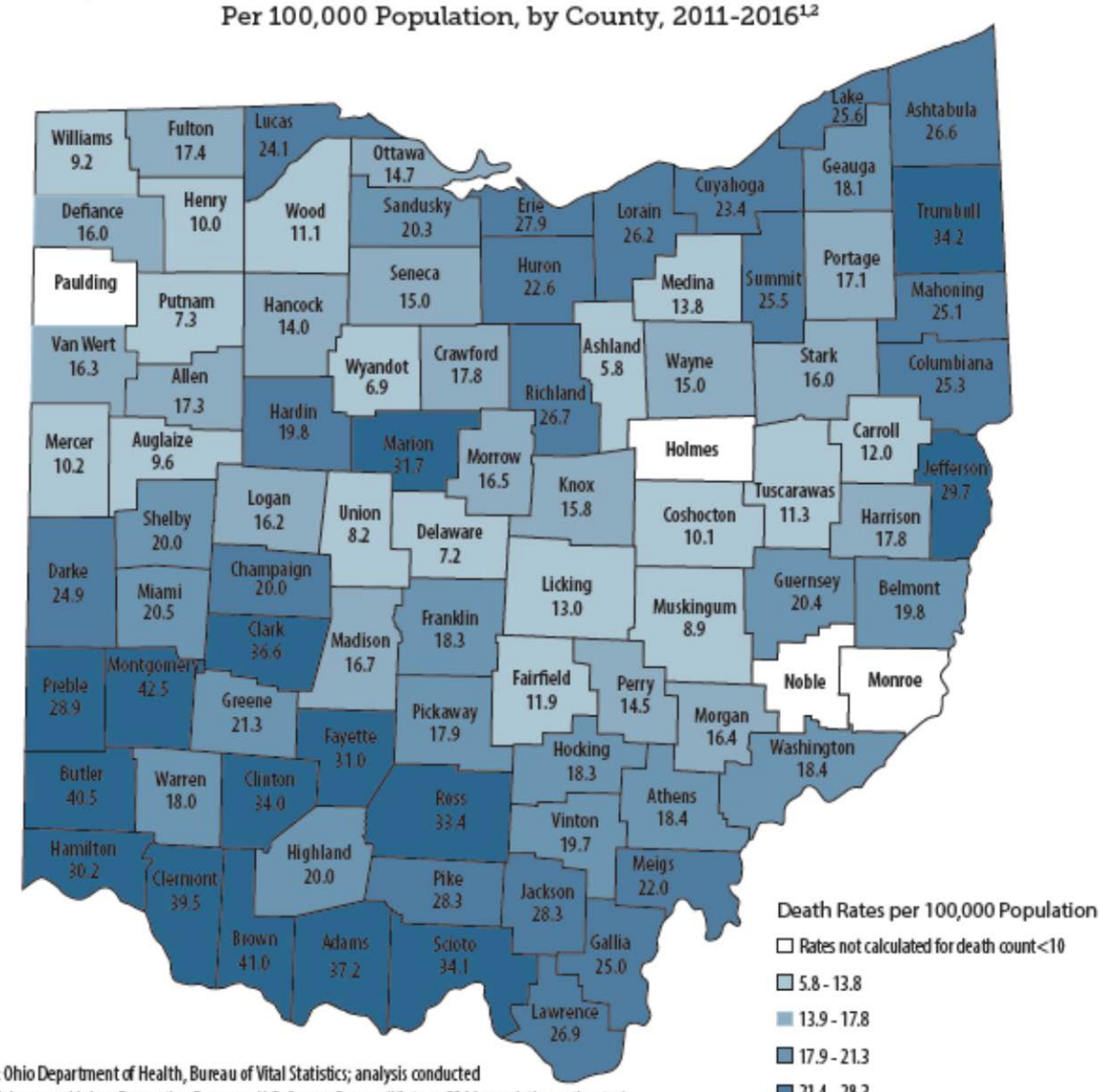
County	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2011-2016 Total	Crude Rate	Age Adjusted Rate
LORAIN	12	13	18	16	18	25	21	25	70	69	71	63	146	444	24.4	26.2

28. As shown in the statistics above, Lorain County has seen a significant spike in overdose deaths due to opioids and some of the highest rates across the State of Ohio and the country as a whole. According to the Ohio Department of Health, from 2011-2016 Lorain County had a 26.2 drug overdose death rate per 100,000 population, which ranked near the top in Ohio:

[13] "Lorain County Opiate Related Deaths 2012-2013", accessed at http://www.publicsafety.ohio.gov/links/OCJS-Lorain-County-Opiate-Related-Deaths.pdf

[14] Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2015 on CDC WONDER Online Database, released December, 2016. Data are from the Multiple Cause of Death Files, 1999-2015, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/ucd-icd10.html on Jul 26, 2017. ICD-10 Codes: X40–X44, X60–X64, X85, and Y10–Y14

Figure 9. Average Age-Adjusted Unintentional Drug Overdose Death Rate Per 100,000 Population, by County, 2011-2016[1,2]



[1] Sources: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program; U.S. Census Bureau (Vintage 2016 population estimates).

[2] Includes Ohio residents who died due to unintentional drug poisoning (underlying cause of death ICD-10 codes X40-X44).

Rate suppressed if < 10 total deaths for 2011-2016.

29. The final week of January, 2016 was the only week last year when a person didn't overdose and die in Lorain County.[15]

[15] "Opioid Overload": County struggles as epidemic widens, accessed at: http://www.chroniclet.com/Local-News/2017/06/11/OPIOID-OVERLOAD-County-struggles-as-epidemic-widens.html

30. According to Lorain County Coroner Dr. Stephan Evans, from 2000 to 2009 there were about 12 ½ overdose deaths per year on average in Lorain County. In 2016, there were about 132, or ten times more. In 2017, Lorain County is on track for over 200 overdose deaths.[16]

31. A steep drop in employment and manufacturing in Ohio, including in Lorain County, has been attributed to the opioid epidemic.[17]

32. Additionally, in the past several years there has been a significant increase in babies born addicted to opiates. Infants spend their first months of life in heavy withdrawal, a condition known as "Neonatal Abstinence Syndrome (NAS)". These children often need years of long term care and monitoring due to NAS.

33. The Lorain County Sheriff's Department has seen a dramatic increase in costs due to the opioid epidemic. This is includes the significant increase in emergency calls made due to overdoses, the use of Narcan, and increased crime related to opiates. The dramatic increase in the use of Narcan and other related drugs, as displayed below, all comes at a cost to the County.

34. The County of Lorain has made significant attempts to fight the epidemic of prescription opioid medications, heroin, and other opioids which have taken over its community. This includes increased law enforcement, educational and community programs, drug support programs, providing Naloxone to its law enforcement and emergency medical providers, as well as others.

35. To address the issue of opioid abuse and death the County has created the Lorain County Drug Task Force The task force has been given the responsibility of educating the community of Lorain and provides education related to opiates.

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17 https://www.forbes.com/sites/adammillsap/2016/10/18/rust-belt-cities-and-moving-to-opportunity-its-time-to-get-back-on-the-hillbilly-highway/#2881ebce7d82

36. The County of Lorain has taken steps and will foreseeably continue to take steps in efforts to combat the opioid epidemic which has been caused by the actions of the Defendants. These government efforts create an increased cost and spending.

37. But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

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

39. Efforts by doctors to reverse course for a chronic pain patient already on opioids long-term include managing the physical suffering and psychological distress a patient endures while withdrawing from the drugs. This process is often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that is diverted to supply them. Even though they never would have prescribed opioids in the first place, many doctors feel compelled to continue prescribing opioids to patients who have become dependent on them.

40. According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in 2010[18], and adolescents are abusing opioids in alarming numbers.

41. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on the County and local agencies that address heroin use and addiction. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013. Heroin produces a very similar high to prescription

[18] CDC, *Presxcription Painkiller Overdoses in the US* (Nov. 2011), https://www.cdc.gov/vitalsigns/painkilleroverdoses/.

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

42. As this data shows, if it were not for the efforts of the County, its first responders and hospitals, the deaths related to heroin and fentanyl would more than double.

43. According to the National Institute on Drug Abuse, based on data collected from a 2013 study, 80% of heroin users reported using prescription opioids prior to heroin.[19]

44. Dr. Robert DuPont, former director of the National Institute on Drug Abuse, opines that opioids are more destructive than crack cocaine:

> [Opioid abuse] is building more slowly, but it's much larger. And the potential[] for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.[20]

45. Countless County residents suffer from chronic pain, which takes an enormous toll on their health, their lives, and their families. These residents deserve both appropriate care and the ability to make decisions based on accurate and complete information about treatment risks and benefits. But Defendants' deceptive and unfair marketing campaign deprived County residents and their doctors of

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[19] https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use

[20] Transcript, *Use and Abuse of Prescription Painkillers*, The Diane Rehm Show (Apr. 21, 2011), http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript.

the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

46. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of Cephalon's labels for Fentora and Actiq) may have allowed, or did not exclude, the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids. Indeed, what makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. Defendants deceptively and unfairly engaged a patient base that—physically and psychologically—could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

47. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians (PCPs), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements. Defendants were also able to callously manipulate what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

48. By 2014, nearly two million Americans were either abusing opioid medications or were dependent on opioids.[21] According to the CDC, opioids have created a "public health epidemic" as of 2016.[22]

49. Defendants' marketing campaign has been extremely harmful and has cost American lives – including lives of residents of the County of Lorain. Deaths from prescription opioids have quadrupled since 1999. From 2000 to 2014 nearly 500,000 people died from such overdoses; seventy-eight Americans die everyday from opioid overdoses.[23]

50. It is estimated that, in 2012, 2.1 million people in the United States suffered from substances use disorders related to prescription opioid pain relievers.[24]

51. 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*."[25] 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

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[21] CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids, Addiction and Overdose. Available at http://www.cdc.gov/drugoverdose/opioids/prescribed.html (accessed May 17, 2017).

[22] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/ts0140429.htm (accessed May 17, 2017).

[23] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic.

[24] 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.

[25] 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 Maybe17, 2017) (emphasis added).

causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

52. The rising numbers of persons addicted to opioids have led not only to an increase in health care costs to the County, and specifically the Plaintiff, but also a major increase in issues such as drug abuse, diversion,[26] and crimes related to obtaining opioid medications. The County of Lorain has been severely and negatively impacted due to the fraudulent misrepresentations and omissions by Defendants regarding the use and risk related to opioids. In fact, Defendants have been and continue to be aware of the high levels of diversion of their product.

53. Due to the conduct of the Defendants, the commission of criminal acts have been undertaken not only by individuals seeking to obtain opioids, but by physicians themselves. The actions of Defendants have created an environment where select physicians have sought to profit at the expense of their patients who become addicted to opioid pain medications, often accepting cash payments and ordering unnecessary medical tests, again at the expense of the County of Lorain.

54. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents.

JURISDICTION AND VENUE

52. This Court has jurisdiction over this action pursuant to 1345.04 (as to the Ohio Consumer Sales Practices Act claim), 4165.01 (as to the Ohio Deceptive Trade Practices Act claim),

[26] The CDC defines using or obtaining opioids illegally as "diversion."

R.C. 2307.382 (as to the Ohio Products Liability Act claim); and 2305.01 (as to the common law public nuisance, common law fraud, unjust enrichment and negligence claims).

52. Venue is proper in Lorain County pursuant to Ohio Civ. R. 3(B)(3), (6) and (7).

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

PARTIES

A. Plaintiff.

54. The County of Lorain is municipality within the state of Ohio, with a population of over 300,000 residents. 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.

55. **Defendants.**

56. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

57. Purdue is primarily engaged in the manufacture, promotion, and distribution of opioids nationally and in the County of Lorain, including the following:

a. OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist[27] tablet first approved in 1995 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to

[27] An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

April 2014,[28] OxyContin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

b. MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

c. Dilaudid (hydromorphone hydrochloride) is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the "management of pain in patients where an opioid analgesic is appropriate."

d. Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."

[28] The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizens' petition by doctors. The changes were intended to clarify the existing obligation to "make an individualized assessment of patient needs." The petitioners also successfully urged that the revised labels heighten the requirements for boxed label warnings related to addiction, abuse, and misuse by changing "Monitor for signs of misuse, abuse, and addiction" to "[Drug name] exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." Letter from Bob Rappaport, Dir. Ctr. for Drug Evaluations & Res., *Labeling Supplement and PMR [Post-Marketing Research] Required* (Sept. 10, 2013), http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf.

e. Butrans (buprenorphine) is a Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Butrans was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

f. Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

54. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

55. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million—at the time one of the largest settlements with a

drug company for marketing misconduct.[29] Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of 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.

56. 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.

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

58. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva USA conducts Teva Ltd.'s sales and marketing activities for Cephalon in the United States and has done so since Teva Ltd.'s October 2011 acquisition of Cephalon. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Lorain, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. (Teva USA and Cephalon, Inc. collectively are referred to herein as "Cephalon.")

59. Cephalon has been in the business of manufacturing, selling, and distributing the following opioids, nationally and in Lorain :

a. Actiq (fentanyl citrate) is a Schedule II opioid agonist lozenge (lollipop) first approved in 1998 and indicated for the "management of breakthrough cancer

[29] https://oig.hhs.gov/publications/docs/press/2007/SemiannualRelfall2007E.pdf

pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

b. Fentora (fentanyl citrate) is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

60. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful promotion to cancer patients experiencing pain. The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug must be prescribed solely to cancer patients. In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million in fines, damages, and penalties.

61. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 through 2009 nationally and within the County of Lorain.

62. On September 29, 2008, Cephalon entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services.[30] The agreement, *inter alia*, required Cephalon to send doctors a letter advising them of the settlement terms and gave them a means to report questionable conduct of its sales representatives; disclose payments to doctors on its web site; and regularly certify that the company has an effective compliance program.

63. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson, a New

[30] https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (accessed May 30, 2017)

Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil- Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica Inc. Defendant Ortho-Mcneil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc.'s stock, and it corresponds with the FDA regarding Janssen's products. Upon information and belief, Johnson & Johnson controls the sale and development of Janssen Pharmaceutical's drugs, and Janssen Pharmaceuticals, Inc.'s profits inure to Johnson & Johnson's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and Johnson & Johnson collectively are referred to herein as "Janssen.")

64. Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in Lorain and the rest of the nation, including Duragesic (fentanyl), which is a Schedule II opioid agonist transdermal patch first approved in 1990 and indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

65. Until January 2015, Janssen also developed, marketed, and sold Nucynta and Nucynta ER:

a. Nucynta ER (tapentadol extended release) is a Schedule II opioid agonist tablet first approved in 2011 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Nucynta ER was indicated for the "management of moderate to severe chronic

pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." The DPN indication was added in August 2012.

b. Nucynta (tapentadol) is a Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older."

66. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.[31] Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

67. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. collectively are referred to herein as "Endo.")

68. Endo develops, markets, and sells prescription drugs, including the following opioids, in the County of Lorain and nationally:

a. Opana ER (oxymorphone hydrochloride extended release) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Opana ER was indicated for the "relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."

[31] http://www.prnewswire.com/news-releases/depomed-announces-closing-of-acquisition-of-us-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-from-janssen-pharmaceuticals-inc-for-105-billion-300060453.html (accessed May 30, 2017)

b. Opana (oxymorphone hydrochloride) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "relief of moderate to severe acute pain where the use of an opioid is appropriate."

c. Percodan (oxycodone hydrochloride and aspirin) is a Schedule II opioid agonist tablet first approved in 1950 and first marketed by Endo in 2004 and indicated for the "management of moderate to moderately severe pain."

d. Percocet (oxycodone hydrochloride and acetaminophen) is a Schedule II opioid agonist tablet first approved in 1999 and first marketed by Endo in 2006 and indicated for the "relief of moderate to moderately severe pain."[32]

69. 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 alone accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids nationally and in the County of Lorain, both itself and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

70. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in March 2015. Prior to that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. in January 2013 and then to Actavis plc in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis

[32] In addition, Endo marketed Zydone (hydrocodone bitartrate and acetaminophen), a Schedule III opioid agonist tablet indicated for the "relief of moderate to moderately severe pain," from 1998 through 2013. The FDA's website indicates this product is currently discontinued, but it appears on Endo's own website.

Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter collectively are referred to as "Actavis.")

71. Actavis engages in the business of marketing and selling opioids in Lorain and across the country, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Kadian (morphine sulfate extended release) is a Schedule II opioid agonist capsule first approved in 1996 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Kadian was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

72. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

73. Insys develops, markets, and sells prescription drugs, including Subsys, a sublingual spray of fentanyl, in Lorain and nationally.

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

75. Defendant McKesson had a net income in excess of $1.5 Billion in 2015.

76. Defendant McKesson distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including New York State and the County of Lorain.

77. Upon information and belief, defendant McKesson is a pharmaceutical distributor licensed to do business in Ohio.

78. Defendant McKesson is the largest pharmaceutical distributor in North America.

79. Upon information and belief, McKesson delivers one-third of all pharmaceuticals used in North America.

80. Defendant McKesson does substantial business in the State of Ohio and the County of Lorain.

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

82. Defendant Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Ohio and the County of Lorain.

83. Upon information and belief, defendant Cardinal is a pharmaceutical distributor licensed to do business in Ohio.

84. Defendant Cardinal does substantial business in the State of Ohio and the County of Lorain.

85. Upon information and belief, defendant Cardinal is one of the largest distributors of opioid pain medications in the Country, including the State of Ohio.

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

87. Defendant Amerisource does substantial business in the State of Ohio and the County of Lorain.

88. Upon information and belief, Defendant Amerisource is a pharmaceutical distributor licensed to do business in the State of Ohio.

89. Defendant Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Ohio and the County of Lorain.

90. Upon information and belief, defendant Amerisource is one of the largest distributors of opioid pain medications in the Country, including the State of Ohio and the County of Lorain.

91. Defendant Miami-Luken, Inc. ("Miami-Luken") is an Ohio corporation with its principal place of business in Springboro, Ohio.

92. Defendant Miami-Luken distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Ohio and the County of Lorain.

93. Upon information and belief, defendant Miami-Luken is a pharmaceutical distributor licensed to do business in Ohio.

94. Defendant Miami-Luken is one of the largest pharmaceutical distributors in North America.

95. Defendant Miami-Luken does substantial business in the State of Ohio and the County of Lorain.

96. The four pharmaceutical distributor defendants (hereinafter "Distributor Defendants") are three of the largest opioid distributors in the Country, the State of Ohio, and within the County of Lorain.

97. The Distributor Defendants purchased opioids from manufacturers, such as the named defendants herein, and sold them to pharmacies throughout Lorain.

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

99. Russell Portenoy, M.D., is an individual residing in New York. Defendant Dr. Portenoy is a physician licensed to practice medicine in the state of New York. Dr. Portenoy was instrumental in promoting opioids for sale and distribution nationally and in the County of Lorain.

100. Perry Fine, M.D., is an individual residing in Utah. Dr. Fine was instrumental in promoting opioids for sale and distribution nationally and in the County of Lorain.

101. Scott Fishman, M.D., is an individual residing in California. Dr. Fishman was instrumental in promoting opioids for sale and distribution nationally and in the County of Lorain.

102. Lynn Webster, M.D., is an individual residing in Utah. Dr. Webster was instrumental in promoting opioids for sale and distribution nationally and in the County of Lorain.

FACTS RELEVANT TO ALL CAUSES OF ACTION

A. Background on Pain Medicine.

1. Safe and Effective Treatment of Chronic Pain Centers on Informed Risk Management.

103. The practice of medicine centers on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as the risk of non-treatment.

104. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risks of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

105. This bedrock principle of full disclosure is particularly important in the context of chronic opioid therapy because of the risk that patients will become physically and psychologically dependent on the drugs, finding it difficult to manage or terminate their use.

106. The FDA-approved drug labels on each of Defendants' opioids do not attempt to advise physicians how to maximize the benefits and minimize the risks for patients on long-term chronic opioid therapy. The labels contain no dosing cap above which it would be unsafe for any

doctor to prescribe to any patient. Nor do any of the labels provide a duration limit, after which the risks to a patient might increase. Thus, doctors and patients rely more heavily on educational materials such as treatment guidelines, CMEs, and scientific and patient education articles and websites to inform their treatment decisions.

2. Opioid Use Is Associated with Known and Substantial Risks.

107. Opium has been recognized as a tool to relieve pain for millennia; so has the magnitude of its potential for abuse, addiction and its dangers. Opioids are related to illegal drugs like opium and heroin. In fact, types of fentanyl, a widely-distributed opioid in the United States, have now been made illegal in China.

108. 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 and beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States.[33] 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.

109. 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.

[33] 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).

110. Studies and articles from the 1970s and 1980s also made the reasons to avoid opioids clear. 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, and even prohibited, the use of opioid therapy for chronic pain.

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

112. 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 to obtain the same levels of pain reduction to which he or she has become accustomed – up to and including doses that are "frighteningly high."[34] 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.

113. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, has explained the effect of opioids as akin to "hijack[ing] the brain's reward system," which in turn convinces a user that "the drug is needed to stay alive."[35] A patient's fear of the

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

[35] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts*, The Orange Cnty. Reg. (Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.

unpleasant effects of discontinuing opioids combined with the negative reinforcement during a period of actual withdrawal can drive a patient to seek further opioid treatment—even where ineffective or detrimental to quality of life—simply to avoid the deeply unpleasant effects of withdrawal.

114. Patients that receive high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to an overdose even when opioids are taken as recommended.

115. Further, "a potential side effect from chronic use [of opioids] can be abuse and addiction . . . . [i]n fact, correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena."[36] It is very difficult to tell whether a patient is physically dependent, psychologically dependent, or addicted. Drug-seeking behaviors, which are signs of addiction, will exist and emerge when opioids are suddenly not available, the dose is no longer effective, or tapering of a dose is undertaken too quickly.

116. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[37]

117. Each of these risks and adverse effects—dependence, tolerance, and addiction—is fully disclosed in the labels for each of Defendants' opioids (though, as described below, not in Defendants'

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[36] Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81(2) Drug & Alcohol Dependence 103, 106 (2006).

[37] Joseph A. Boscarino et al., *Risk factors for drug daependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction 1776 (2010); Joseph A. 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).

marketing).[38] Prior to Defendants' deceptive marketing scheme, each of these risks was well-recognized by doctors and seen as a reason to use opioids to treat chronic pain sparingly and only after other treatments had failed.

118. 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.

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

120. Defendant Purdue was aware that its drug OxyContin did not provide pain relief for up to 12 hours. Purdue was also aware of the risk that patients would then take additional pain medications, beyond what was prescribed, to make of up for that gap in time. Despite this knowledge, Purdue continued to market OxyContin as lasting for 12 hours.

121. While it was once thought that long-acting opioids would not be as susceptible to abuse and addiction as short-acting ones, this view has been discredited. OxyContin's label now states, as do all labels of Schedule II long-acting opioids, that the drug "exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." The FDA has required extended release and long-acting opioids to adopt "Risk Evaluation Mitigation Strateg[ies]" on the basis that they present "a serious public health crisis of addiction, overdose, and death."[39]

[38] For example, Purdue's OxyContin label (October 5, 2011) states: "Physical dependence and tolerance are not unusual during chronic opioid therapy."

[39] FDA, *Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting*

122. In 2013, in response to a petition to restrict the labels of long-acting opioid products, the FDA noted the "grave risks" of opioids, "the most well-known of which include addiction, overdose, and even death."[40] The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death."[41] The FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks in their labels. Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain— that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended release opioids "should be used ***only when alternative treatments are inadequate***."[42]

123. Notably, in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

124. The FDA-approved labels on each of Defendant's opioids do not attempt to advise physicians on how to maximize the benefits and minimize the risks for patients on long term opioid therapy. The labels contain no dosage cap above which it would be unsafe to prescribe to any patient. Nor do they provide a duration limit. Doctors and patients rely heavily on education materials, such as treatment guidelines, CMEs, and scientific and patient education articles and websites, to inform their treatment decisions.

125. On July 25, 2012, the Physicians for Responsible Opioid Prescribing ("PROP"), a non-profit organization made up of doctors and other health care professionals, petitioned the FDA to change the labeling of opioid medications. The petition was signed by thirty-seven physicians located

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Opioids (last updated Oct. 9, 2014), http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm.

[40] 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).

[41] *Id.*

[42] *Id.* at 7 (emphasis in original).

nationwide. In its letter to the FDA, the group stated that "an increasing body of medical literature suggests that long term-use of opioids may be neither safe nor effective for many patients, especially when prescribed in high doses."[43]

126. In its petition, PROP also stated that "many clinicians are under the false impression that chronic opioid therapy ("COT") is an evidence-based treatment for chronic non-cancer pain" and that "these misconceptions lead to overprescribing and high dose prescribing." It was also their opinion that "the current label on opioid analgesics does not comply with [FDA law]".

127. As the basis for its petition, PROP provided "Statements of Scientific Basis for Petition" which provided a list of detailed reports and studies proving the risks of opioid medications, the high risk of addiction, the exaggerated and false benefits, and further medically backed reasons to change the labelling of opioid medications to reduce prescribing.

128. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life- threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[44] The FDA required that – going forward – opioid makers of long-acting formulations clearly communicate these risks on their labels.

129. 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

[43] July 25, 2012 letter from PROP to FDA, accessed at http://www.citizen.org/documents/2048.pdf on May 17, 2017.

[44] 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).

changes across all prescription opioid products to include additional information on the risk of these medications.[45]

130. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants in the many years since they began marketing these drugs.

3. Long-Term Opioid Use Benefits Are Unproven and Contradicted.

131. Despite the fact that opioids are now routinely prescribed, there has never been evidence of their safety and efficacy for long-term use.

132. Defendants have always been aware of these gaps in knowledge. While promoting opioids to treat chronic pain, Defendants have failed to disclose the lack of evidence to support their long-term use and have failed to disclose the contradictory evidence that chronic opioid therapy actually makes patients sicker.

133. 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. The first random, placebo-controlled studies appeared in the 1990s, and revealed evidence only for short-term efficacy and only in a minority of patients.[46]

134. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and showed that, while opioids had short-term efficacy, the data was insufficient to establish long-term effectiveness. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently note the lack of data to assess long-term outcomes. For example, a 2007 systematic review of opioids

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[45] 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 May 17, 2017).

[46] Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin J. Pain 303 (2007); Roger Chou et al., *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).

for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain).

135. On the contrary, evidence exists to show that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."[47] Another review of evidence relating to the use of opioids for chronic pain found that up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids, and that the evidence of pain relief over time was weak.

136. Endo's own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

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

138. As a pain specialist noted in an article titled *Are We Making Pain Patients Worse?*, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as

[47] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (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. 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 (2012).

does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[48]

139. This 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. Conversely, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not help patients return to work or to physical activity. This is due partly to addiction and other side effects.

140. 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 (MIDAS), and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

141. The lack of evidence for the efficacy of opioid use long-term has been well-documented nationally in the context of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who take opioids are almost four times as likely to reach costs of over $100,000 than claims treated without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, taking an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would be on work disability one year later. A prescription for opioids, as the first treatment for a workplace injury, doubled the average length of the claim.

4. Defendants' Impact on the Perception and Prescribing of Opioids.

[48] Andrea Rubenstein, *Are we making pain patients worse?*, Sonoma Medicine (Fall 2009).

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

143. In 1986, the World Health Organization ("WHO") published an "analgesic ladder" for the treatment of cancer pain.[49] The WHO recommended treatment with over-the- counter or prescription acetaminophen or non-steroidal anti-inflammatory drugs ("NSAIDs") first, and then the use of unscheduled or combination opioids, and then stronger (Schedule II or III) opioids if pain persisted. The WHO ladder pertained only to the treatment of cancer pain, and did not contemplate the use of narcotic opioids for chronic pain—because the use of opioids for chronic pain was not considered appropriate medical practice at the time.

144. Studies and articles from the 1970s and 1980s made the reasons to avoid opioids clear. 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.

145. In 1986, Defendant 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

[49] http://apps.who.int/iris/bitstream/10665/43944/1/9241561009_eng.pdf (accessed May 30, 2017)

"[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[50]

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

> The traditional approach to chronic nonmalignant 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.*[51] (Emphasis provided)

According to Portenoy, these 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."[52]

147. For the reasons outlined by Dr. Portenoy, and in the words of one researcher from the Harvard Medical School, "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids."[53] Defendants changed that perception.

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[50] Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).
[51] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994) (emphasis added).
[52] *Id.*
[53] Igor Kissin, *Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?*, 6 J. Pain Research 513, 514 (2013) (quoting Loeser JD, *Five crises in pain management*, 20(1) Pain Clinical Updates 1-4 (2012).

B. Defendants Promoted Their Branded Products Through Direct Marketing to Prescribers and Consumers.

148. Defendants' direct marketing proceeded on two tracks, serving two related purposes. First, Defendants worked through branded and unbranded marketing to build confidence in long-term opioid use by overstating its benefits and downplaying its risks, thereby expanding the chronic pain market. In addition, Defendants worked through their own staffs of sales representatives, physician speakers whom those representatives recruited, and advertising in medical journals to claim their share of that broader market. Defendants directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

1. Defendants Relied Upon Branded Advertisements.

149. Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. Defendants' advertising budgets peaked in 2011, when they collectively spent more than $14 million on the medical journal advertising of opioids, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.[54]

150. A number of these branded advertisements deceptively portrayed the benefits of opioid therapy for chronic pain. As just one example, a 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life

[54] In 2011, Actavis spent less than $100,000 on such advertising, and Cephalon spent nothing. These companies' medical journal advertising peaked earlier, with Actavis spending $11.7 million in 2005, and Cephalon spending about $2 million in each of 2007 and 2008.

With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described below, are unsubstantiated and contradicted in medical literature.

2. Defendants Relied Upon Their Sales Forces and Recruited Physician Speakers.

151. Each Defendant promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual physicians and their staff in their offices—and small group speaker programs. By establishing close relationships with doctors, Defendants' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain. Representatives were trained on techniques to build these relationships, with Actavis even rolling out an "Own the Nurse" kit as a "door opener" to time with doctors.

152. Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health. This data allows them to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their appeals.

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

154. Defendants' sales representatives have visited hundreds of thousands of doctors, including thousands of visits to County prescribers, and as described herein, spread misinformation

regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. This misinformation includes deceptive and unfair claims regarding the risks of opioids for chronic pain, particularly the risks of addiction, withdrawal, and high doses, as well as the benefits.

155. Each Defendant carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of that company's drugs specifically, and opioids in general. Pharmaceutical companies exactingly direct and monitor their sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and other means—to ensure that individual detailers actually deliver the desired messages and do not veer off-script. Pharmaceutical companies likewise require their detailers to deploy sales aids reviewed, approved, and supplied by the company and forbid them to use, in industry parlance, "homemade bread"—*i.e.*, promotional materials not approved by the company's marketing and compliance departments. Sales representatives' adherence to their corporate training is typically included in their work agreements. Departing from their company's approved messaging can, and does, lead to severe consequences including termination of employment.

156. Besides carefully training their sales representatives, Defendants used surveys of physicians—conducted by third-party research firms—to assess how well their core messages came across to prescribers.

157. In addition to making sales calls, Defendants' detailers also identified doctors to serve, for payment, on Defendants' speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. Defendants almost always selected physicians who were "product loyalists," as they were sure to be asked whether they prescribe the drug themselves. Endo, for instance, sought to use specialists in pain medicine—including high prescribers of its drugs—as local "thought leaders" to market Opana ER to primary care doctors. Such invitations are lucrative to the physicians selected for

these bureaus; honorarium rates range from $800 to $2,000 per program, depending on the type of event, speaker training is typically compensated at $500 per hour.

158. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; a forum in which to further market to the speaker him or herself; and an opportunity to market to the speaker's peers. Defendants grade their speakers and future opportunities are based on speaking performance, post-program sales, and product usage. Defendants also track the prescribing of event attendees, with Endo noting that "physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than before." It would make little sense for Defendants to devote significant resources to programs that did not increase their sales.

159. Like the sales representatives who select them, speakers are expected to stay "on message"—indeed, they agree in writing to follow the slide decks provided to them. Endo's speaker rules, for example, provide that "all slides must be presented in their entirety and without alterations . . . and in sequence." This is important because the FDA regards promotional talks as part of product labeling, and requires their submission for review. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by Defendants' marketing departments. Although these meal-based speaker events are more expensive to host, and typically have lower attendance than CMEs, they are subject to less professional scrutiny and thus afford Defendants greater freedom in the messages they present.

160. Defendants devoted massive resources to these direct sales contacts with prescribers. In 2014, Defendants collectively spent $168 million on detailing branded opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The total figure is more than double Defendants' collective spending on detailing in 2000. Detailers' role in Defendants' overall

promotional efforts was also carefully calibrated; Endo, for example, found that devoting 61% of its marketing budget to sales representatives reflected an "[a]ppropriate combination of personal . . . and non-personal . . . selling initiatives."

161. 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,[55] and face-to-face detailing has the highest influence on intent to prescribe. 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 of Defendants' drugs.

3. Defendants Directed These Promotional Efforts Through Detailed Marketing Plans.

162. Defendants guided their efforts to expand opioid prescribing through comprehensive marketing and business plans for each drug. These documents, based on the companies' extensive market research, laid out ambitious plans to bring in new prescribers and increase overall prescribing of Defendants' opioids.

a. Targeting categories of prescribers

163. Defendants targeted, by zip codes and other local boundaries, individual health care providers for detailing. Defendants chose their targets based on the potential for persuading a provider

[55] *See, e.g.,* Puneet Manchanda & Pradeep K. 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); Ian 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* Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

to prescribe, ease of in-person access, and the likelihood of higher numbers of prescriptions at higher doses, with no correlation to demonstrated need or demand for opioid therapy, or to risk of abuse.

164. Collectively, Defendants' marketing plans evince dual strategies, which often operated parallel to one another. Defendants' sales representatives continued to focus their detailing efforts on pain specialists and anesthesiologists, the highest-volume prescribers of opioids and, as a group, more educated than other practitioners about opioids' risks and benefits. Seeking to develop market share and expand sales, however, Defendants also targeted increasing numbers and types of prescribers for marketing.

165. This expanded market of prescribers was, as a group, less informed about opioids and, as market research concluded, more susceptible to Defendants' marketing messages. These prescribers included nurse practitioners and physician assistants who, a 2012 Endo business plan noted, were "share acquisition" opportunities because they were "3x times more responsive than MDs to details" and wrote "96% of [their] prescriptions . . . without physician consult."

166. The expanded market also included internists and general practitioners who were low- to mid-volume prescribers. Actavis, for example, rolled out a plan in 2008 to move beyond "Kadian loyalists" to an "expanded audience" of "low morphine writers."

b. Increasing "direct to consumer" marketing

167. Defendants knew that physicians were more likely to prescribe their branded medications when patients asked for those medications. Endo's research, for example, found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physician's office, as well as employer and workers' compensation plan initiatives to, as Endo put it, "[d]rive

demand for access through the employer audience by highlighting cost of disease and productivity loss."

168. Defendants also knew that one of the largest obstacles to patients starting and remaining on their branded opioids—including by switching from a competitor's drug—was out- of-pocket cost. They recognized they could overcome this obstacle by providing patients financial assistance with their insurance co-payments, and each of the Defendants did so through vouchers and coupons distributed during detailing visits with prescribers. A 2008 Actavis business review, for example, highlighted co-pay assistance, good for up to $600 per patient per year, as a way to drive conversions to Kadian from competitor drugs like Avinza and MS Contin. In 2012, Janssen planned to distribute 1.5 million savings cards worth $25 each.

c. Differentiating each brand

169. Purdue's OxyContin was the clear market leader in prescription opioid therapy, with 30% of the market for analgesic drugs in 2012. However, by 2010, Defendants had begun facing increasing pushback from the medical community and regulators based on the growing problems of opioid addiction and abuse. Both market conditions prompted Defendants to pursue product differentiation strategies—particularly an emphasis on their products being less subject to diversion, abuse, and addiction—as a means of grabbing market share from Purdue and other competitors.

170. Endo, for example, tracked in detail prescriber "switching" from OxyContin to Opana ER. Actavis and Janssen did the same for switches to Kadian and Nucynta ER, respectively. Pressure to stand out among other drugs resulted in Defendants identifying marketing themes that thereafter were reflected in Defendants' deceptive and harmful messages to physicians and consumers. A 2008 Janssen plan emphasized "value" messaging in support of Nucynta ER, including claims of less dose escalation, lower toxiCounty, fewer withdrawal symptoms, and less dependence, and a 2009 Opana ER

market research report focused on greater potency and lower abuse potential of Opana ER vis-à-vis OxyContin.

d. Moving beyond office visits

171. Defendants sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. For their sales forces, these included marketing to prescribers through voice mail, postcards, and email—so- called "e-detailing." Defendants also created new platforms for their speakers by implementing "peer to peer" programs such as teleconferences and webinars that were available to prescribers nationally. These programs allowed Defendants to use this more seemingly credible vehicle to market to, among other hard-to-reach audiences, prescribers at hospitals, academic centers, and other locations that limit or prohibit in-person detailing. Employing these new approaches, each Defendant relied heavily on speakers to promote its drugs.

4. Defendants Marketed Opioids in Lorain Using the Same Strategies and Messages They Employed Nationwide.

172. Defendants employed the same marketing plans and strategies and deployed the same messages in Lorain as they did nationwide.

173. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

174. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide

decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide desks, and supervisors traveled with them periodically to check on both their performance and compliance.

175. As they did nationwide, Defendants extensively tracked the prescribing behavior of County-area health care providers and used that data to target their detailing and speaker- recruiting efforts. Top prescribers were profiled at the County, region, zip code, and sometimes facility levels, with information about their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Providers' prescribing volume was ranked and sorted into deciles.

176. As described herein, misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic pain were part and parcel of Defendants' marketing campaigns in Lorain .

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

177. In addition to their direct marketing efforts, Defendants used unbranded, third- party marketing, which they deployed as part of their national marketing strategies for their branded drugs. Each Defendant executed these strategies through a network of third-party KOLs and Front Groups, with which it acted in concert by funding, assisting, encouraging, and directing their efforts. At the same time, Defendants exercised substantial control over the content of the messages third parties generated and disseminated, and distributed certain of those materials themselves. As with their other marketing strategies, Defendants' unbranded marketing created, and relied upon, an appearance of independence and credibility that was undeserved but central to its effectiveness. Unlike their direct promotional activities, Defendants' unbranded marketing allowed them to evade the oversight of federal regulators and gave them greater freedom to expand their deceptive messages.

1. Regulations Governing Branded Promotion Require that it Be Truthful, Balanced, and Supported by Substantial Evidence.

178. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. 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.[56] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

179. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") 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."[57] "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended."[58] "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.[59] "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.[60] Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

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[56] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).
[57] 21 U.S.C. §§ 352.
[58] 21 C.F.R. § 201.5.
[59] 21 U.S.C. § 321(m).
[60] *See id.*

180. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to ***any*** presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included."[61] Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

181. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study."[62] Further, drug companies must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[63]

182. While the FDA must approve a drug's label, it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.[64] Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; 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

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[61] FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, May 2009, at 14.

[62] 21 C.F.R. § 99.101(a)(4).

[63] 21 C.F.R. § 202.1(e)(6)(ii).

[64] *See* 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").

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.

2. Defendants Deployed Front Groups and Doctors to Disseminate Unbranded Information on Their Behalf.

183. Drug companies market both directly and indirectly, using third party validators (such as scientists, physicians, or patient or professional organizations) that appear to be independent and therefore more credible. The FDA has made clear that its promotional requirements apply to both forms of marketing:

> FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf.
>
> . . . .
>
> Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third- party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.[65]

184. In addition to being carried out directly or through third parties, 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 sidestep the extensive regulatory framework governing branded communications.

185. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically

[65] FDA, *Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, January 2014, at 1, 4, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf.

contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

186. Even where such unbranded messages were channeled 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. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. *See* 21. C.F.R. 202.1(e)(7)(l)(2).[66] Defendants' sales representatives distributed third-party marketing material that was deceptive to Defendants' target audiences. Defendants are responsible for these materials.

187. Moreover, Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Defendants

[66] This regulation provides: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act." As labeling, such third party-created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

exercised control over their deceptive messages and acted in concert[67] with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

188. For example, drug companies have been admonished for making functional claims in FDA-reviewed branded materials because there is no evidence for such claims. Thus, drug companies were put on notice that the FDA would not allow such claims in branded materials. Defendants instead created and disseminated these same unsupported claims—that opioids allow patients to sleep, return to work, or walk more easily—through *unbranded* marketing materials.

189. The third-party publications Defendants assisted in creating and distributing did not include the warnings and instructions mandated by their FDA-required drug labels and consistent with the risks and benefits known to Defendants. For example, these publications either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

190. By acting through third parties, Defendants were able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent third parties. Later, Defendants would cite to these sources as "independent" corroboration of their own statements. As one physician adviser to Defendants noted, third-party documents not only had greater credibility, but broader distribution as doctors did not "push back" at having materials from, for example, the non-profit American Pain Foundation ("APF") on display in their offices, as they might with first party, drug company pieces. Nevertheless, the independence of these materials was a ruse—Defendants were in close contact with these third parties, paid for and were aware of the misleading information they were disseminating about the use of opioids to treat chronic pain, and regularly helped them to tailor and distribute their misleading, pro-opioid messaging.

[67] As used in this Complaint, the allegation that Defendants "acted in concert" with third parties is intended to mean *both* that they conspired with these third parties to achieve some end and that they aided and abetted these third parties in the commission of acts necessary to achieve it.

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

a. Defendants' Use of KOLs

192. Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Defendants by touting the benefits of opioids to treat chronic pain.

193. 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. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) 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.

194. In return, the KOLs' association with Defendants provided not only money, but prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community.

195. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could

be relied on to help broaden the chronic opioid therapy market. Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.[68] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

196. Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy. Indeed, one prominent KOL sponsored by Defendants, Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding. Some KOLs have even gone on to become direct employees and executives of Defendants, like Dr. David Haddox, Purdue's Vice President of Risk Management, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

197. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

198. Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences. Since 2000, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

[68] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

199. These KOLs were carefully vetted to ensure that they were likely to remain on-message and supportive of a pharmaceutical industry agenda. One measure was a doctor's prior work for trusted Front Groups.

200. Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances they also scripted what these KOLs said—as they did with all their recruited speakers. The KOLs knew, or deliberately ignored, the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Defendants, all the while causing harm to County prescribers and patients.

i. *Defendant Russell Portenoy*

201. Defendant Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

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

203. Defendant Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast in Lorain and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a

person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[69]

204. Defendant Dr. Portenoy has recently admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[70] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[71]

ii. *Defendant Lynn Webster*

205. Another KOL, Defendant Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake County, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy.[72] He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

206. Dr. Webster had been under investigation for overprescribing by the DEA, which raided his clinic in 2010. More than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five

[69] Good Morning America television broadcast, ABC News (Aug. 30, 2010).
[70] hThomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.
[71] *Id.*
[72] Journal supplements are paid for by drug manufacturers and, although they may be designed to blend into the rest of the journal, are not peer-reviewed and constitute drug company advertising.

question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach County doctors.

207. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[73]

b. <u>"Research" That Lacked Supporting Evidence</u>

208. Rather than find a way to actually test the safety and efficacy of opioids for long- term use, Defendants led people to believe that they already had. 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

[73] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb. 19, 2012).

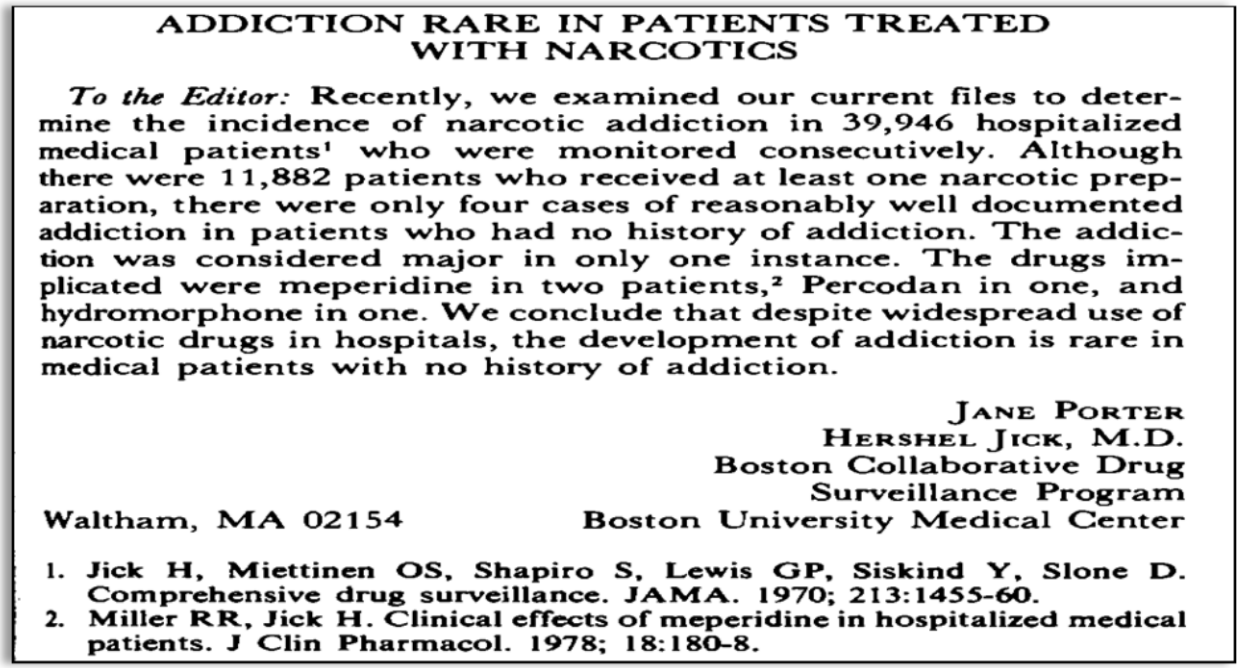
research; and (c) was thus more likely to shape the perceptions of prescribers, patients and payors. This literature was, in fact, marketing material focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

209. To accomplish this, Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. Defendants' internal documents reveal plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort, "fast-track" application journals, that they could use if the pending paper was rejected everywhere else.

210. Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. The 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, but in Defendants' marketing departments and with Defendants' marketing and public relations consultants. Defendants often relied on "data on file" or presented posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

211. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study. Most notably, Purdue promoted a 1980 reference 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"). It is cited 856 times in Google Scholar, and 86 times since 2010. It also

appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.[74] Defendants and those acting on their behalf fail to reveal that this "article" is actually a letter-to-the-editor, not a peer-reviewed study (or any kind of study at all). The Porter-Jick Letter, reproduced in full below, describes a review of the charts of hospitalized patients who had received opioids. (Because it was a 1980 study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.)



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

212. The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. None of these serious limitations is disclosed when Defendants, or those acting on their behalf, cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.

[74] AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; "Chronic Pain Management and Opioid Use," October 11, 2012, sponsored by Purdue. Each CME is available for online credit, including to prescribers in Lorain County.

213. Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury 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—targeted a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

214. Defendants' strategies—first, to plant and promote supportive literature and then, to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicts those claims—are flatly inconsistent with their legal obligations. The strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns.

c. Treatment Guidelines

215. 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 otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Furthermore, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

i. *FSMB*

216. 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.

217. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB admitted was produced "in collaboration with pharmaceutical companies."[75] The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

218. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These guidelines were posted online and were available to and intended to reach County physicians.

219. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

220. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), and the FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale. The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

221. Drug companies relied on FSMB guidelines to convey the message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head—doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

222. FSMB, more recently, has moderated its stance. Although the 2012 revision of *Responsible Opioid Prescribing* continued to teach that "pseudoaddiction" is real and that opioid addiction risk can be managed through risk screening, it no longer recommended chronic opioid therapy as a first choice after the failure of over-the-counter medication and has heightened its addiction and risk warnings.

ii. *AAPM/APS Guidelines*

223. AAPM and the APS are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013 (with AAPM receiving over $2 million).

224. They issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[76] The co-author of the statement, Dr. Haddox, was, at the time, a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.[77]

[76] Consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), *available at* http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf.
[77] *Id.*

225. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[78] Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

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

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

iii. *American Geriatrics Society*

228. The American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients

[78] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) The Journal of Pain: Official Journal of the American Pain Society 113-130 (2009)

with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[79] These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

229. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Defendants including Endo and Purdue beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they had approved the message, AGS ceded significant control to these companies. Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

230. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[80] Five of 10 of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock. The Institute of

[79] Pharmacological Management of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2009.00699.x/full.

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

Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

iv. *Guidelines That Did Not Receive Defendants' Support*

231. 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. 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 improvement in physical and functional status and minimal adverse effects."[81]

232. 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

[81] 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).

costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.[82]

233. 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 the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . .; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . .; lack of evidence on the utility of informed consent and opioid management plans . . .; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.[83]

d. Continuing Medical Education

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

235. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants

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

[83] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010), *available at* http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf.

aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

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

237. 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 educational subject matter."[84]

238. Dozens of CMEs that were available to and attended or reviewed by County doctors during the relevant time period did not live up to the AMA's standards.

239. The influence of Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non- industry-funded CME

[84] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), *available at* http://eo2.commpartners.com/users/ama/downloads/120328_Opinion_E-9_0115.pdf.

mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.[85]

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

e. Unbranded Patient Education

241. 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."[86] Evidence also demonstrates that physicians are willing to acquiesce to patient demands for a particular drug— even for opioids and for conditions for which they are not generally recommended.[87] An Actavis marketing plan, for example, noted that "[d]irect-to-consumer marketing affects prescribing decisions." Recognizing this fact, Defendants put

[85] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), *available at* pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf.

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

[87] Prescribers often accede to patient requests. According to one study, nearly 20% of sciatica patients requesting oxycodone would receive a prescription for it, compared with 1% making no request. More than half of patients requesting a strong opioid received one. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

242. The drug companies expect that they will recoup their investment in direct-to-consumer advertisements by capturing at least some of any additional prescriptions that result from patients "asking their doctor" about drugs that can treat their pain. Doctors also may review direct-to-consumer materials sales representatives give them to distribute to patients.

f. Defendants' Use of Front Groups

243. As noted above, Defendants Cephalon, Endo, Janssen, and Purdue entered into arrangements with numerous 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; 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.

i. *American Pain Foundation*

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

245. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF

also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach County residents.

246. In addition to Perry Fine, Russell Portenoy, and Scott Fishman, who served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

247. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

248. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. As laid out below, APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

249. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group

conferences, suggested activities and publications APF could pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

250. APF assisted in other marketing projects for drug companies. One project funded by another drug company—*APF Reporter's Guide: Covering Pain and Its Management* (2008)[88]—recycled text that was originally created as part of the company's training document.

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

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

253. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[89]

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[88] https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf (accessed May 30, 2017)

[89] http://www.painfoundation.org (last visited May 17, 2017).

ii. *The American Academy of Pain Medicine*

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

255. AAPM has received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintains a corporate relations council, whose members pay $25,000 per year (on top of other funding) to participate. The benefits include allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors.

256. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

257. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr.

Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[90]

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

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

259. Like cigarette manufacturers, 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 present the risks, benefits, and superiority of opioids to treat chronic pain.

260. 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. These KOLs have worked reciprocally with Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to Lorain prescribers and patients.

261. One vehicle for their collective 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 to "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the Forum as "a deliberate

[90] 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.

effort to positively merge the capacities of industry, professional associations, and patient organizations."

262. 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 (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other like-minded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants.

263. 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.[91] This was critical as a REMS that went too far in narrowing the uses or benefits, or highlighting the risks of chronic opioid therapy, would deflate Defendants' marketing efforts. The recommendations—drafted by Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers."[92] Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

[91] 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.
[92] Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

4. Defendants Targeted Vulnerable and Lucrative Populations.

a. The Elderly

264. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as Defendants acknowledge in their labels (but not in their marketing), occurs more frequently in elderly patients. A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs. Defendants' targeted marketing to the elderly and the absence of cautionary language in their promotional materials flies in the face of scientific evidence and their own labels, and creates a heightened risk of serious injury to elderly patients.

265. Defendants also promoted the notion—also without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. AGS's 2009 Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse." Yet, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

266. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

b. Veterans

267. Veterans, too, are suffering greatly from the effects of Defendants' targeted marketing. A 2008 survey showed that prescription drug abuse among military personnel had doubled from 2002 to 2005, and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they had in 2001. Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days.

Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving VA services nationally in a single year (2005), 1,013 had died of an accidental drug overdose—double the rate of the civilian population.

268. The County has a substantial population of veterans who must cope with the consequences of overprescribing opioids.

269. Opioids are particularly dangerous to veterans. According to a study published in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death. According to a VA Office of Inspector General Report, despite the risks, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines.[93] Again, as with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids pose to them.

270. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, and written as a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications." The book also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards."

[93] https://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf (accessed May 30, 2017)

As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

271. *Exit Wounds* minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which were taken by a significant number of veterans.[94] It is not the unbiased narrative of a returning war veteran. It is pure marketing, sponsored by Purdue, Endo, and Janssen. Janssen, for example, supported the marketing effort, and its insufficient disclosures, despite acknowledging on the label for its opioid Duragesic that its use with benzodiazepines "may cause respiratory depression, hypotension, and profound sedation or potentially result in coma." A similar warning is found on the labels of other Defendants' opioids.

272. The deceptive nature of *Exit Wounds* is obvious in comparing it to guidance on opioids published by the VA and DOD in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death—none of which is disclosed in *Exit Wounds*.

C. Why Defendants' Marketing Messages Are Misleading and Unfair

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

[94] FDA guidance states that materials designed to target a particular audience should disclose risks particular to that audience. *See* FDA Notice, Guidance for Industry, "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs," August 6, 2015.

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

274. There are seven primary misleading and unfounded representations. Defendants and the third parties with which they teamed:

- misrepresented that opioids improve function;
- concealed the link between long-term use of opioids and addiction;
- misrepresented that addiction risk can be managed;
- masked the signs of addiction by calling them "pseudoaddiction";
- falsely claimed withdrawal is easily managed;
- misrepresented or omitted the greater dangers from higher doses of opioids; and
- deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

275. In addition to these misstatements, Purdue purveyed an eighth deception that OxyContin provides a full 12 hours of pain relief.

276. Exacerbating each of these misrepresentations and deceptions was the collective effort of Defendants and third parties to hide from the medical community the fact that the FDA "is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[95]

1. Defendants and Their Third-Party Allies Misrepresented that Opioids Improve Function

277. Each of the following materials was created with the expectation that, by instructing patients and prescribers that opioids would improve patients' function and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to

[95] 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).

continue opioid therapy in the belief that failure to improve pain, function, or quality of life, could be overcome by increasing doses or prescribing supplemental short-acting opioids on an as-needed basis for breakthrough pain.

278. However, not only is there no evidence of improvement in long-term functioning, but a 2006 study-of-studies found that "[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids."[96] Studies of the use of opioids in chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. 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. [97] Indeed, one Defendant's own internal marketing plans characterized functional improvement claims as "aspirational." Another acknowledged in 2012 that "[s]ignificant investment in clinical data [was] needed" to establish opioids' effect on mitigating quality of life issues, like social isolation.

279. The long-term use of opioids carries a host of serious side effects, including addiction, mental clouding and confusion, sleepiness, hyperalgesia, and immune-system and hormonal dysfunction that degrade, rather than improve, patients' ability to function. Defendants often omitted these adverse effects as well as certain risks of drug interactions from their publications.

280. Yet each of the following statements by Defendants, suggests that the long-term use of opioids improve patients' function and quality of life, and that scientific evidence supports this claim.

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[96] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

[97] Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. They also were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy." (Emphasis added.) b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function. c. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and cause patients to enjoy their lives. The FDA warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[98] d. Actavis sales representatives told Lorain prescribers that prescribing Actavis's opioids would improve their patients' ability to function and improve their quality of life.

Cephalon	e. Cephalon sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists. f. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks associated with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report. The publication is also currently available online. g. Cephalon sponsored a CME written by key opinion leader Dr. Lynn Webster,

[98] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18. 2010), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm.

	titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, to December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long- acting opioids. h. Cephalon sales representatives told Lorain prescribers that opioids would increase patients' ability to function and improve their quality of life.

Endo	i. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. j. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." k. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[99] l. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007) which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." m. Endo provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. n. Endo sales representatives told Lorain prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

[99] FDA regulations require that warnings or limitations be given equal prominence in disclosure, and failure to do so constitutes "misbranding" of the product. 21 C.F.R. § 202.1(e)(3); *see also* 21 U.S.C. §331(a).

Janssen	o. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved, and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative backing for the claims that does not exist. The targeting of older adults also ignored heightened opioid risks in this population p. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative. This video is still available today on youtube.com. q. 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). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. r. Janssen sales representatives told Lorain prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

Purdue	s. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain vignettes," which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, "Paul," is described as a "54-year- old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively. t. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" had shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The *Policymaker's Guide* is still available online. u. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain*

	(2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 annual report. The guide is currently available online. v. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. w. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book. x. Purdue sales representatives told Lorain prescribers that opioids would increase patients' ability to function and improve their quality of life.

2. Defendants and Their Third-Party Allies Concealed the Truth About the Risk of Addiction from Long-Term Opioid Use

281. The fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic pain patients Defendants, and the Front Groups and KOLs that they directed, assisted, and collaborated with, had to overcome doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk—condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for Defendants' campaign to convince doctors otherwise, finding benefits from opioid use for common chronic pain conditions sufficient to justify that risk would have, and previously had, posed a nearly insurmountable challenge.

282. Through their well-funded, comprehensive marketing efforts, Defendants and their KOLs and Front Groups were able to change prescriber perceptions despite the well-settled historical understanding and clear evidence that opioids taken long-term are often addictive. Defendants and their third-party partners: (a) brazenly maintained that the risk of addiction for patients who take

opioids long-term was low; and (b) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk—and Defendants' own labels—compelled disclosure.

283. Further, in addition to falsely claiming opioids had low addiction risk or omitting disclosure of the risk of addiction altogether, Defendants employed language that conveyed to prescribers that the drugs had lower potential for abuse and addiction. Further, in addition to making outright misrepresentations about the risk of addiction, or failing to disclose that serious risk at all, Defendants used code words that conveyed to prescribers that their opioid was less prone to abuse and addiction. For instance, sales representatives for Actavis, Endo, Janssen, and Purdue promoted their drugs as having "steady-state" properties with the intent and expectation that prescribers would understand this to mean that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction. Further, Endo actively promoted its reformulated Opana ER on the basis that it was "designed to be crush-resistant," suggesting both (a) that Endo had succeeded in making the drug harder to adulterate, and (b) that it was less addictive, in consequence. In fact, however, Endo knew that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER" and that Opana ER could still be ground and cut into small pieces by those looking to abuse the drug. In the same vein, Janssen denied that Nucynta ER was an opioid and claimed that it was not addictive, and Purdue claimed that its opioids were not favored by addicts and did not produce a buzz, all of which falsely suggested that its opioids were less likely to be abused or addictive.

284. Each of the following was created with the expectation that, by instructing patients and prescribers that addiction rates are low and that addiction is unlikely when opioids are prescribed for pain, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue—APF's 2011 *A Policymaker's Guide to Understanding Pain & Its Management*—

claimed that opioids are not prescribed often enough because of "misconceptions about opioid addiction."[100]

285. Acting directly or with and through third parties, each of the Defendants claimed that the potential for addiction from its drugs was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted them. A recent literature survey found that while ranges of "problematic use" of opioids ranged from <1% to 81%,[101] abuse averaged between 21% and 29% and addiction between 8% and 12%.[102] These estimates are well in line with Purdue's own studies, showing that between 8% and 13% of OxyContin patients became addicted, but on which Purdue chose not to rely, instead citing the Porter-Jick letter.

286. The FDA has found that 20% of opioid patients use two or more pharmacies, 26% obtain opioids from two or more prescribers, and 16.5% seek early refills—all potential "red flags" for abuse or addiction.[103] The FDA in fact has ordered manufacturers of long-acting opioids to "[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain," in recognition of the fact that it found "high rates of addiction" in the medical literature.[104]

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[100] http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (accessed May 30, 2017)

[101] Cited for the low end of that range was the 1980 Porter-Jick letter in the *New England Journal of Medicine*.

[102] Kevin Vowels et al., *Ratesof opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, 156 PAIN 569-76 (April 2015).

[103] Len Paulozzi, M.D., "Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse," *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM233244. pdf

[104] September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics*, available at* http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf ; 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).

287. Of course, the significant (and growing) incidence of abuse, misuse, and addiction to opioids is also powerful evidence that Defendants' statements regarding the low risk of addiction were, and are, untrue. This was well-known to Defendants who had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

288. Acting directly or through and with third parties, each of the Defendants claimed that the potential for addiction even from long-term use of its drugs was relatively small, or non- existent, despite the fact that the contention was false and there was no scientific evidence to support it. Examples of these misrepresentations are laid out below:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction. b. Actavis had a patient education brochure distributed in 2007 that claimed addiction is possible, but it is "less likely if you have never had an addiction problem." Although the term "less likely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. c. Kadian sales representatives told Lorain prescribers that Kadian was "steady state" and had extended release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused. d. Kadian sales representatives told Lorain prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused—and thereby less addictive—than other opioids. e. Kadian sales representatives omitted any discussion of addiction risks related to Actavis's drugs to County prescribers.
Cephalon	f. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which claims, among other things, that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

	g. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. h. Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon's drugs to County prescribers.
Endo	i. Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence. j. Endo's advertisements for the 2012 reformulation of Opana ER claimed it was *designed to be crush resistant*, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse" and Endo's "post-"post-marketing date submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse. k. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests the risk is so low as not to be a concern. The language also implies that, as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. l. Endo sponsored a website, PainAction.com, which stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." m. Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult* and *Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients[,]" which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients. n. Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." o. Endo distributed a patient education pamphlet edited by key opinion leader Dr. Russell Portenoy titled *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 pain patients prescribed opioids will not become addicted, which is unsupported and untrue. p. Endo contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion. q. Endo sales representatives told Lorain prescribers that its drugs were "steady state," the implications of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. r. Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the risk is so low as not to be a concern. s. Endo sales representatives omitted discussion of addiction risks related to Endo's drugs.
Janssen	t. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." Although the term "rarely" is not defined, the overall presentation suggests the risk is so low as not to be a concern. The language also implies that as long as a prescription is given, opioid use is not a problem. u. Janssen contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide

	this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion. v. Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that [l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. w. Janssen currently runs a website, *Prescriberesponsibly.com* (last modified July 2, 2015), which claims that concerns about opioid addiction are "overstated." x. A June 2009 Nucynta Training module warns Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed." y. Janssen sales representatives told Lorain prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. z. Janssen sales representatives told Lorain prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen's drugs. In truth, however, as set out in Nucynta's FDA-mandated label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit." aa. Janssen's sales representatives told Lorain prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug. bb. Janssen sales representatives omitted discussion of addiction risks related to Janssen's drugs.

Purdue	dd. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, "Indications of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use.[105] Thus, these misrepresentations wrongly reassure doctors that, as long as they do not observe those signs, they need not be concerned that their patients are abusing or addicted to opioids. ee. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication is still available online. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction." ff. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. gg. A Purdue-funded study with a Purdue co-author claimed that "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[106] The study relied only on the Porter-Jick letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. Although the term "low" is not defined, the overall presentation suggests the risk is so low as not to be a worry. hh. Purdue contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

[105] Purdue itself submitted briefing materials in October 2010 to a meeting of the FDA's Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee in which it stated that OxyContin was used non-medically by injection 4-17% of the time.

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

	ii. Purdue sponsored APF's *Exit Wounds* (2009), which counseled veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests it is so low as not to be a worry. jj. Purdue sales representatives told Lorain prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. kk. Purdue sales representatives told Lorain prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamper-proof and, after a certain point, patients no longer experience a "buzz" from increased dosage. ll. Advertisements that Purdue sent to Lorain prescribers stated that OxyContin ER was less likely to be favored by addicts, and, therefore, less likely to be abused or diverted, or result in addiction. mm. Purdue sales representatives omitted discussion of addiction risks related to Purdue's drugs.

289. In addition to denying or minimizing the risk of addiction and abuse generally, Defendants also falsely claimed that their particular drugs were safer, less addictive, and less likely to be abused or diverted than their competitors' or predecessor drugs. In making these claims, Defendants said or implied that because their drug had a "steady-state" and did not produce peaks and valleys, which cause drug-seeking behavior—either to obtain the high or avoid the low—it was less likely to be abused or addicting. Endo also asserted in particular that, because a reformulation of Opana ER was (or was designed to be) abuse-deterrent or tamper-resistant, patients were less likely to become addicted to it. Defendants had no evidence to support any of these claims, which, by FDA regulation, must be based on head-to-head trials;[107] the claims also were false and misleading in that they misrepresented the risks of both the particular drug and opioids as a class.

[107] *See Guidance for Industry*, "Abuse-Deterrent Opioids—Evaluation and Labeling," April 2015 (describing requirements for premarket and postmarket studies).

290. Further, rather than honestly disclose the risk of addiction, Defendants, and the third parties they directed and assisted and whose materials they distributed, attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables; it was doctors who fail to treat their patients' chronic pains with opioids—not doctors who cause their patients to become addicted to opioids—who are failing their patients (and subject to discipline). Defendants and their third-party allies claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. This mantra of under-treated pain and under-used drugs reinforced Defendants' messages that the risks of addiction and abuse were not significant and were overblown.

291. For example, Janssen's website, *Let's Talk Pain*, warns in a video posted online that "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: "Because of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients . . . . This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

292. In the same vein, a Purdue website called *In the Face of Pain* complains, under the heading of "Protecting Access," that, through at least mid-2013, policy governing the prescribing of opioids was "at odds with" best medical practices by "unduly restricting the amounts that can be prescribed and dispensed"; "restricting access to patients with pain who also have a history of substance abuse"; and "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe." This unsupported and untrue rhetoric

aims to portray doctors who do not prescribe opioids as uncaring, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

3. Defendants and Their Third-Party Allies Misrepresented that Addiction Risk Can Be Avoided or Managed

293. To this day, defendants each continue to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted. Presumably only to explain why doctors encounter so many patients addicted to opioids, Defendants and their third-party allies have come to admit that some patients could become addicted, but that doctors can 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.

294. There are three fundamental flaws in these assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. Second, there is no reliable scientific evidence that high-risk or addicted patients can take opioids long-term without triggering addiction, even with enhanced monitoring and precautions. Third, there is no reliable scientific evidence that patients without these red flags are necessarily free of addiction risk.

295. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. A recent 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."[108] Furthermore, attempts to treat high-risk patients, such as 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, if busy doctors even in fact attempt them.

296. Most disturbingly, despite the widespread use of screening tools, patients with past substance use disorders—which every tool rates as a risk factor—receive, on average, higher doses of opioids.

297. Each Defendant claimed that the risk of addiction could be avoided or managed, claims that are deceptive and without scientific support:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction.
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."
Endo	c. Endo paid for a 2007 supplement[109] available for continuing education credit in the Journal of Family Practice. This publication, titled Pain Management Dilemmas in Primary Care: Use of Opioids, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely (e.g., without becoming addicted) receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
Purdue	d. Purdue's unbranded website, In the Face of Pain (inthefaceofpain.com) states that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-

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

[109] The Medical Journal, *The Lancet* found that all of the supplement papers it received failed peer-review. Editorial, "The Perils of Journal and Supplement Publishing," 375 *The Lancet* 9712 (347) 2010.

	issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds with" best medical practices.[110] e. Purdue sponsored a 2012 CME program taught by a KOL titled Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior. f. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, titled Managing Patient's Opioid Use: Balancing the Need and Risk. This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." g. Purdue sales representatives told Lorain prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction.

4. Defendants and Their Third-Party Allies Created Confusion By Promoting the Misleading Term "Pseudoaddiction."

298. Defendants and their third-party allies developed and disseminated each of the following misrepresentations with the intent and expectation that, by instructing patients and prescribers that signs of addiction are actually the product of untreated pain, doctors would prescribe opioids to more patients and continue to prescribing them, and patients would continue to use opioids despite signs that the patient was addicted. The concept of "pseudoaddiction" was coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, who consulted for Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction," as if patients could not experience both. As KOL Dr. Lynn Webster wrote:

[110] *See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment*, Purdue Pharma L.P. (Resources verified Mar. 2012), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf.

"[Pseudoaddiction] obviously became too much of an excuse to give patients more medication.. . . It led us down a path that caused harm. It is already something we are debunking as a concept."[111]

299. Each of the publications and statements below falsely states or suggests that the concept of "pseudoaddiction" is substantiated by scientific evidence and accurately describes the condition of patients who only need, and should be treated with, more opioids:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."
Cephalon	b. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of "pseudoaddiction." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.
Endo	c. Endo distributed copies of a book by KOL Dr. Lynn Webster entitled Avoiding Opioid Abuse While Managing Pain (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as "pseudoaddiction" and thus, increasing the dose in most cases . . . should be the clinician's first response." (emphasis added). d. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."
Janssen	e. From 2009 to 2011 Janssen's website, Let's Talk Pain, stated that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."(emphasis added).

[111] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb.19, 2012).

Purdue	f. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which described "pseudoaddiction" as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." g. Purdue distributed to physicians, at least as of November 2006, and posted on its unbranded website, *Partners Against Pain*, a pamphlet copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct, including "illicit drug use and deception" it defined as indicative of "pseudoaddiction" or untreated pain. It also states: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when *pain is undertreated*. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be *distinguished from true addiction* in that the behaviors resolve when the pain is effectively treated." (Emphasis added.) h. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name, "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction." Purdue also spent over $100,000 to support distribution of the book. i. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (Emphasis added.)

5. Defendants and Their Third-Party Allies Claimed Withdrawal is Simply Managed

300. Defendants and their third-party allies promoted the false and misleading messages below with the intent and expectation that, by misrepresenting the difficulty of withdrawing from opioids, prescribers and patients would be more likely to start chronic opioid therapy and would fail to recognize the actual risk of addiction.

301. In an effort to underplay the risk and impact of addiction, Defendants and their third-party allies frequently claim that, while patients become "physically" dependent on opioids, physical dependence can be addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal. They fail to disclose the extremely difficult and painful effects that patients can experience

when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

302. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy. Common symptoms of withdrawal include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

303. Each of the publications and statements below falsely states or suggests that withdrawal from opioids was not a problem and they should not be hesitant about prescribing or using opioids:

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

	or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER. d. Janssen sales representatives told Lorain prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids.
Purdue	e. 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 did not disclose the significant hardships that often accompany cessation of use. f. Purdue sales representatives told Lorain prescribers that the effects of withdrawal from opioid use can be successfully managed. g. Purdue sales representatives told Lorain prescribers that the potential for withdrawal on Butrans was low due to Butrans's low potency and its extended release mechanism.

6. Defendants and Their Third-Party Allies Misrepresented that Increased Doses Pose No Significant Additional Risks

304. Each of the following misrepresentations was created with the intent and expectation that, by misrepresenting and failing to disclose the known risks of high dose opioids, prescribers and patients would be more likely to continue to prescribe and use opioids, even when they were not effective in reducing patients' pain, and not to discontinue opioids even when tolerance required them to reach even higher doses.

305. Defendants and their third-party allies 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 also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

306. These claims are false. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The FDA has itself acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction.

307. Each of the following claims suggests that high-dose opioid therapy is safe:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis's opioid, Kadian.
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed. c. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, Optimizing Opiod Treatment for Breakthrough Pain, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations. d. Cephalon sales representatives assured Lorain prescribers that opioids were safe, even at high doses.

Endo	e. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that opioids may be increased until "you are on the right dose of medication for your pain," and once that occured, further dose increases would not occur. Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it. f. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled Understanding Your Pain: Taking Oral Opioid Analgesics. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief."
Janssen	g. Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines and omitted any discussion of risks of increased doses of opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."
Purdue	h. Purdue's In the Face of Pain website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what—in their view—is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands. i. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones. This suggested that high dose opioids are safe and appropriate and did not disclose the risks from high dose opioids. This publication is still available online. j. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses. k. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit. l. Purdue sales representatives told Lorain prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses.

7. Defendants and Their Third-Party Allies Deceptively Omitted or Minimized Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment.

308. Each of the following misrepresentations was created with the intent and expectation that, by omitting the known, serious risks of chronic opioid therapy, including the risks of addiction, abuse, overdose, and death, and emphasizing or exaggerating risks of competing products, prescribers and patients would be more likely to choose opioids. Defendants and their third-party allies routinely ignored the risks of chronic opioid therapy. These include (beyond the risks associated with misuse, abuse, and addiction): hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[112] hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions).[113]

309. Despite these serious risks, Defendants asserted, or implied, that opioids were appropriate first-line treatments and safer than alternative treatments, including NSAIDs such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Defendants' exaggerated descriptions of those

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[112] 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).

[113] Several of these risks do appear in the FDA-mandated warnings. *See, e.g.,* the August 13, 2015 OxyContin Label, Section 6.2, identifying adverse reactions including: "abuse, addiction … death, … hyperalgesia, hypogonadism . . . mood altered . . . overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria [hives]."

risks were deceptive in themselves, and made their omissions regarding the risks of opioids all the more striking and misleading. Defendants and their third-party allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000-20,000 deaths annually (more than opioids), when in reality the number is closer to 3,200. This description of NSAIDs starkly contrasted with their representation of opioids, for which the listed risks were nausea, constipation, and sleepiness (but not addiction, overdose, or death). Compared with NSAIDs, opioids are responsible for roughly four times as many fatalities annually.

310. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.

311. Each of the following reflects Defendants' deceptive claims and omissions about the risks of opioids, including in comparison to NSAIDs:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs. b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, for older persons. c. Kadian sales representatives told Lorain prescribers that NSAIDs were more toxic than opioids.
Cephalon	d. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. e. Cephalon sales representatives told County prescribers that NSAIDs were

	more toxic than Cephalon's opioids
Endo	f. Endo distributed a "case study" to prescribers titled Case Challenges in Pain Management: Opioid Therapy for Chronic Pain. The study cites an example, meant to be representative, of a patient "with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years), and recommends treating with opioids instead. g. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. h. Endo provided grants to APF to distribute *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. i. Endo sales representatives told Lorain prescribers that NSAIDs were more toxic than opioids.
Janssen	j. Janssen sponsored a patient education guide titled Finding Relief: Pain Management for Older Adults (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," "increase [in] the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation. k. Janssen sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines. Janssen's label for Duragesic, however, states that use with benzodiazepines "may cause respiratory depression, [low blood pressure], and profound sedation or potentially result in coma. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. l. Janssen sales representatives told Lorain prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is, in fact, an opioid and has the same effects as other opioids.

Purdue	m. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. n. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. o. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013; The 2013 version is still available for CME credit. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses. p. Purdue sales representatives told Lorain prescribers that NSAIDs were more toxic than opioids.

8. Purdue Misleadingly Promoted OxyContin as Providing 12 Hours of Relief

312. In addition to making the deceptive statements above, Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action.

313. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was, upon information and belief, adapted from Purdue's own sales materials:[114]

[114] Jim Edwards, "*How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*," *CBSNews.com*, Sept. 28, 2011, http://www.cbsnews.com/news/how-purdue-used-misleading-charts-to- hide-oxycontins-addictive-power/. The 160 mg dose is no longer marketed. Purdue's promotional materials in the past displayed a logarithmic scale, which gave the misleading impression the concentration remained constant.

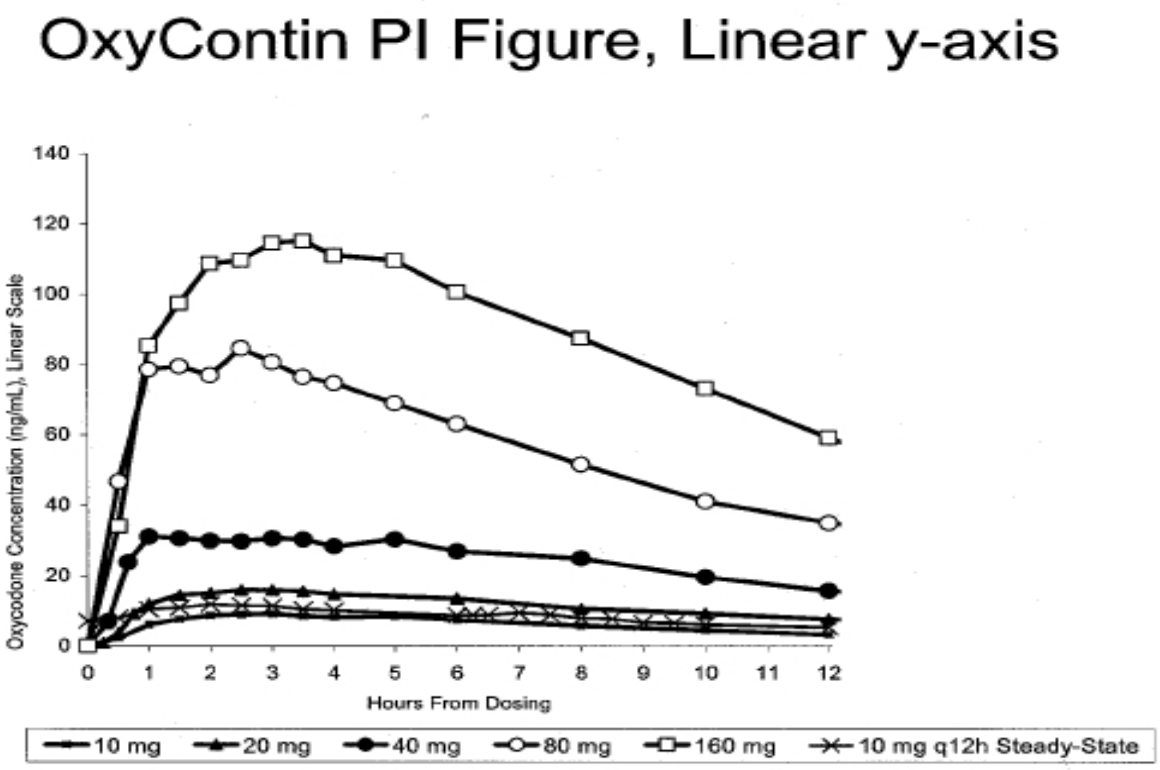


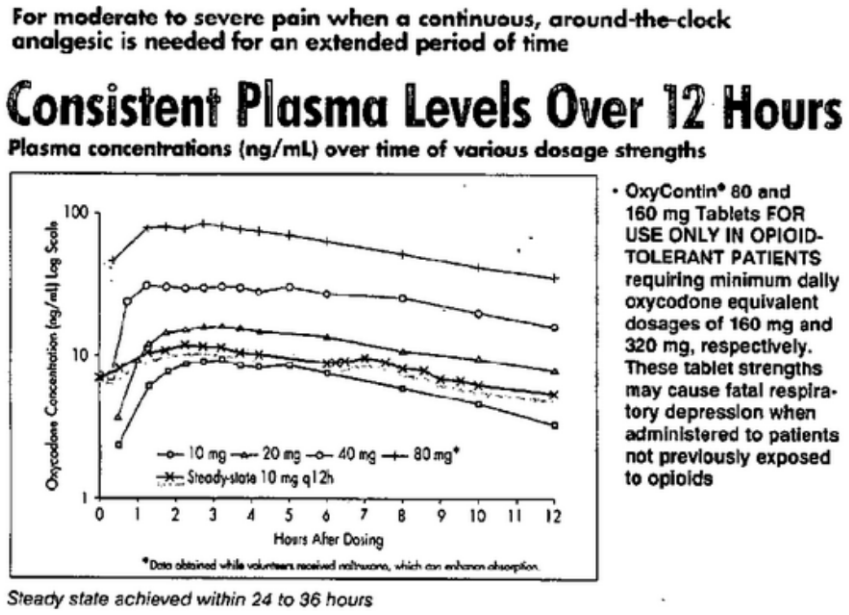
Figure 1

The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the 12 hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

314. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid—OxyContin is roughly twice as powerful as morphine—triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full 12 hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients

will experience "end-of-dose failure" with OxyContin.) The combination of fast onset and end-of-dose failure makes OxyContin particularly addictive, even compared with other opioids.

315. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full 12 hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart depicting plasma levels on a logarithmic scale. The chart minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:



316. More recently, other Purdue advertisements also emphasized "Q12h" (meaning twice-daily) dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. Other advertisements that ran in the 2005 and 2006 issues of the *Journal of Pain* depict a sample prescription for OxyContin, with "Q12h" handwritten for emphasis.

317. The information that OxyContin did not provide pain relief for a full 12 hours was known to Purdue, and Purdue's competitors, but was not disclosed to general practitioners. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two (which would have compensated for end-of-dose failure) was set out in Purdue's internal documents as early as 1999 and is apparent from MEDWATCH Adverse Event reports for OxyContin.[115] Even Purdue's competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering "durable" pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

318. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers in Lorain were not informed of risks relating to addiction, and that they received the misleading message that OxyContin would be effective for treating chronic pain for the advertised duration. Furthermore, doctors would compensate by increasing the dose or prescribing "rescue" opioids, which had the same effect as increasing the amount of opioids prescribed to a patient.[116, 117]

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[115] MEDWATCH refers to the FDA's voluntary adverse event reporting system.

[116] Purdue's *Clinical Issues in Opioid Prescribing*, put out in 2005 under Purdue's unbranded *Partners Against Pain* banner, states that "it is recommended that a supplementary immediate-release medication be provided to treat exacerbations of pain that may occur with stable dosing." References to "rescue" medication appear in publications Purdue sponsored such as APF's *A Policymaker's Guide* (2011) and the 2013 CME *Overview of Pain Management Options*.

[117] The Connecticut Attorney General's office filed a citizens' petition with the FDA on January 27, 2004, requesting that the OxyContin label be amended with a warning not to prescribe the drug more than twice daily as a means of compensating for end-of-dose failure. The FDA denied this request on September 11, 2008. The FDA found that the state had failed to present sufficient evidence that more frequent dosing caused adverse outcomes, but the FDA did not challenge the Connecticut finding that end-of-dose failure of OxyContin was prevalent. Indeed, the FDA found that end-of-dose failure affected a "substantial" number of chronic pain patients prescribed OxyContin.

D. Each Defendant Engaged in Deceptive Marketing, Both Branded and Unbranded, that Targeted and Reached County Prescribers.

319. Defendants—and the Front Groups and KOLs who depended on and worked alongside them—were able to affect a sea change in medical opinion in favor of accepting opioids as a medically necessary long-term treatment for chronic pain. As set forth below, each Defendant contributed to that result through a combination of both direct marketing efforts and third-party marketing efforts over which that Defendant exercised editorial control. These deceptive and misleading statements were directed to, and reached, County prescribers and patients, with the intent of distorting their views on the risks, benefits, and superiority of opioids for treatment of chronic pain.

320. Defendants engaged in their deceptive marketing campaign, both nationwide and in Lorain , using a number of strategies. Defendants trained their sales forces and recruited physician speakers to deliver these deceptive messages and omissions, and they in turn conveyed them to prescribers. Defendants also broadly disseminated promotional messages and materials, both by delivering them personally to doctors during detailing visits and by mailing deceptive advertisements directly to prescribers. Because they are disseminated by Defendant drug manufacturers and relate to Defendants' drugs, these materials are considered "labeling" within the meaning of 21 C.F.R. § 1.3(a), which means Defendants are liable for their content.

321. As described below, the County has located a number of County-area prescribers who received Defendants' misrepresentations. Each of the misrepresentations received by these doctors constitutes an integral piece of a centrally directed marketing strategy to change medical perceptions regarding the use of opioids to treat chronic pain. Defendants were aware of each of these misrepresentations, and Defendants approved of them and oversaw their dissemination at the national, corporate level.

1. Acatvis

322. As described below, Actavis promoted its branded opioid, Kadian, through a highly deceptive marketing campaign, carried out principally through its sales force and recruited physician speakers. As internal documents indicate, this campaign rested on a series of misrepresentations and omissions regarding the risks, benefits, and superiority of opioids, and indeed incorporated each of the types of deceptive messages. Based on the highly coordinated and uniform nature of Actavis's marketing, Actavis conveyed these deceptive messages to County prescribers. Actavis did so with the intent that County prescribers and/or consumers would rely on the messages in choosing to use opioids to treat chronic pain.[118]

a. Actavis' Deceptive Direct Marketing

323. To help devise its marketing strategy for Kadian, Actavis commissioned a report from one of its consultants in January 2005 about barriers to market entry. The report concluded that two major challenges facing opioid manufacturers in 2005 were (i) overcoming "concerns regarding the safety and tolerability" of opioids, and (ii) the fact that "physicians have been trained to evaluate the supporting data before changing their respective practice behavior." To address these challenges, the report advocated a "[p]ublication strategy based on placing in the literature key data that influence members of the target audience" with an "emphasis . . . on ensuring that the message is believable and relevant to the needs of the target audience." This would entail the creation of "effective copy points . . . backed by published references" and "developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect profile." According to the report, this would allow physicians to "reach[] a mental agreement" and change their "practice behavior" without having first evaluated supporting data—of which Actavis (and other Defendants) had none.

[118] Actavis also sold various generic opioids, including Norco, which were widely prescribed in Lorain and benefited from Actavis's overall promotion of opioids, but were not directly marketed by sales representatives.

324. The consulting firm predicted that this manufactured body of literature "w[ould], in turn, provide greater support for the promotional message and add credibility to the brand's advocates" based on "either actual or ***perceived*** 'scientific exchange"' in relevant medical literature. (emphasis added). To this end, it planned for three manuscripts to be written during the first quarter of 2005. Of these, "[t]he neuropathic pain manuscript will provide evidence demonstrating KADIAN is as effective in patients with presumptive neuropathic pain as it is in those with other pain types"; "[t]he elderly subanalysis . . . will provide clinicians with evidence that KADIAN is efficacious and well tolerated in appropriately selected elderly patients" and will "be targeted to readers in the geriatrics specialty"; and "[t]he QDF/BID manuscript will . . . .call attention to the fact that KADIAN is the only sustained-release opioid to be labeled for [once or twice daily] use." In short, Actavis knew exactly what each study would show—and how that study would fit into its marketing plan—before it was published. Articles matching Actavis's descriptions later appeared in the *Journal of Pain* and the *Journal of the American Geriatrics Society*.

325. To ensure that messages based on this science reached individual physicians, Actavis deployed sales representatives, or detailers, to visit prescrs in Lorain and across the country. At the peak of Actavis's promotional efforts in 2011, the company spent $6.7 million on detailing.

326. To track its detailers' progress, Actavis's sales and marketing department actively monitored the prescribing behavior of physicians. It tracked the Kadian prescribing activity of individual physicians, and assessed the success of its marketing efforts by tabulating how many Kadian prescriptions a prescriber wrote after he or she had been detailed. As described below, Kadian monitored numerous County physicians.

327. Actavis also planned to promote Kadian by giving presentations at conferences of organizations where it believed it could reach a high concentration of pain specialists. Its choice of conferences was also influenced by the host's past support of opioids. For example, Actavis

documents show that Actavis presented papers concerning Kadian at an annual meeting of AGS because AGS's guidelines "support the use of opioids."

328. Actavis targeted prescribers using both its sales force and recruited physician speakers, as described below.

i. *Actavis' Deceptive Sales Training*

329. Actavis's sales representatives targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in delivering Actavis's marketing strategies and talking points to individual prescribers.

330. Actavis's strategy and pattern of deceptive marketing is evident in its internal training materials. A sales education module titled "Kadian Learning System" trained Actavis's sales representatives on the marketing messages—including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in Lorain

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331. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids. First, Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have required them to receive increasing doses: "Although tolerance and dependence do occur with long-term use of opioids, many

studies have shown that tolerance is limited in most patients with [Chronic pain]." Second, Actavis instructed its sales personnel that opioid "[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose." Actavis failed to explain to its sales representatives and, through them, to doctors, the greater risks associated with opioids at high doses.

332. Further, the 2010 sales training module highlighted the risks of alternate pain medications without providing a comparable discussion of the risks of opioids, painting the erroneous and misleading impression that opioids are safer. Specifically, the document claimed that "NSAIDs prolong the bleeding time by inhibiting blood platelets, which can contribute to bleeding complications" and "can have toxic effects on the kidney." Accordingly, Actavis coached its sales representatives that "[t]he potential toxiCounty of NSAIDs limits their dose and, to some extent, the duration of therapy" since "[t]hey should only be taken short term." By contrast, the corresponding section related to opioids neglects to include a *single* side effect or risk associated with the use of opioids, including from long-term use.

333. This sales training module also severely downplayed the main risk associated with Kadian and other opioids—addiction. It represented that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction" and, instead, "[i]t appears likely that most substance-abusing patients in pain management practices had an abuse problem before entering the practice." This falsely suggests that few patients would become addicted, that only those with a prior history of abuse are at risk of opioid addiction, and that doctors could screen for those patients and safely prescribe to others. To the contrary, opioid addiction affects a significant population of patients; while patients with a history of abuse may be more prone to addiction, all patients are at risk, and doctors may not be able to identify, or safely prescribe to, patients at greater risk.

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

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

336. The sales training module also directed representatives to counsel doctors to be on the lookout for the signs of "[p]seudoaddiction," which were defined as "[b]ehaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain." However, the concept of "pseudoaddiction" is unsubstantiated and meant to mislead doctors and patients about the risks and signs of addiction.

337. Finally, the 2010 national training materials trivialized the harms associated with opioid withdrawal by explaining that "[p]hysical dependence simply requires a tapered withdrawal should the opioid medication no longer be needed." This, however, overlooks the fact that the side effects associated with opiate withdrawal are severe and a serious concern for *any person* who wishes to discontinue long-term opioid therapy.

338. The Kadian Learning System module dates from July 2010, but Actavis sales representatives were passing deceptive messages on to prescribers even before then. A July 2010 "Dear Doctor" letter issued by the FDA indicated that "[b]etween June 2009 and February 2010, Actavis

sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]." Certain risks that were misrepresented included the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion." The FDA also took issue with an advertisement for misrepresenting Kadian's ability to help patients "live with less pain and get adequate rest with less medication," when the supporting study did not represent "substantial evidence or substantial clinical experience."

339. Actavis's documents also indicate that the company continued to deceptively market its drugs after 2010. Specifically, a September 2012 Kadian Marketing Update, and the "HCP Detail" aid contained therein, noted that Kadian's "steady state plasma levels" ensured that Kadian "produced higher trough concentrations and a smaller degree of peak-to-trough fluctuations" than other opioids.

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

341. Finally, the internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines with doctors during detailing visits. These guidelines deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories.

ii. *Actavis' Deceptive Speaking Training*

342. Actavis also increasingly relied on speakers—physicians whom Actavis recruited to market opioids to their peers—to convey similar marketing messages. Actavis set a goal to train 100 new Kadian speakers in 2008 alone, with a plan to set up "power lunch teleconferences" connecting speakers to up to 500 participating sites nationwide. Actavis sales representatives, who were required to make a certain number of sales visits each day and week, saw the definition of sales call expanded to accommodate these changes; such calls now included physicians' "breakfast & lunch meetings with Kadian advocate/speaker."

343. A training program for Actavis speakers included training on many of the same messages found in the Kadian Learning System, as described below. The deceptive messages in Actavis's speakers' training are concerning for two reasons: (a) the doctors who participated in the training were, themselves, prescribing doctors, and the training was meant to increase their prescriptions of Kadian; and (b) these doctors were trained, paid, and directed to deliver these messages to other doctors who would write prescriptions of Kadian.

344. Consistent with the training for sales representatives, Actavis's speakers' training falsely minimized the risk of addiction posed by long-term opioid use. Actavis claimed, without scientific foundation, that "[o]pioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction." The training also deceptively touted the effectiveness of "Risk Tools," such as the Opioid Risk Tool, in determining the "risk for developing aberrant behaviors" in patients being considered for chronic opioid therapy. In recommending the use of these screening tools, the speakers' training neglected to disclose that none of them had been scientifically validated.

345. The speakers' training also made reference to "pseudoaddiction" as a "[c]ondition characterized by behaviors, such as drug hoarding, that outwardly mimic addiction but are in fact driven by a desire for pain relief and usually signal undertreated pain." It then purported to assist doctors in identifying those behaviors that *actually* indicated a risk of addiction from those that did not.

Behaviors it identified as "[m]ore suggestive of addiction" included "[p]rescription forgery," "[i]njecting oral formulations," and "[m]ultiple dose escalations or other nonadherence with therapy despite warnings." Identified as "[l]ess suggestive of addiction" were "[a]ggressive complaining about the need for more drugs," "[r]equesting specific drugs," "[d]rug hoarding during periods of reduced symptoms," and "[u]napproved use of the drug to treat another symptom." By portraying the risks in this manner, the speakers' training presentation deceptively gave doctors a false sense of security regarding the types of patients who can become addicted to opioids and the types of behaviors these patients exhibit.

346. The speakers' training downplayed the risks of opioids, while focusing on the risks of competing analgesics like NSAIDs. For example, it asserted that "Acetaminophen toxiCounty is a major health concern." The slide further warned that "Acetaminophen poisoning is the most common cause of acute liver failure in an evaluation of 662 US Subjects with acute liver failure between 1998-2003," and was titled "Opioids can be a safer option than other analgesics." However, in presenting the risks associated with opioids, the speakers' training focused on nausea, constipation, and sleepiness, and ignored the serious risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness; increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines. As a result, the training exaggerated the risks of NSAIDs, both absolutely and relative to opioids, to make opioids appear to be a more attractive first-line treatment for chronic pain.

347. The speakers' training also misrepresented the risks associated with increased doses of opioids. For example, speakers were instructed to "[s]tart low and titrate until patient reports adequate analgesia" and to "[s]et dose levels on [the] basis of patient need, not on predetermined maximal dose." However, the speakers' training neglected to warn speakers (and speakers bureau attendees) that patients on high doses of opioids are more likely to suffer adverse events.

b. Actavis's Deceptive Statements to County of Lorain Prescribers and Patients

348. The misleading messages and training materials Actavis provided to its sales force and speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and alternatives. This deception was national in scope and included Lorain . Actavis's nationwide messages reached Lorain prescribers in a number of ways. For example, they were carried into Lorain by Actavis's sales representatives during detailing visits as well as made available to County patients and prescribers through websites and ads, including ads in prominent medical journals. They have also been delivered to County prescribers by Actavis's paid speakers, who were required by Actavis policy and by FDA regulations to stay true to Actavis's nationwide messaging.

349. Once trained, Actavis's sales representatives and speakers were directed to, and did, visit potential prescribers in Lorain as elsewhere, to deliver their deceptive messages. These contacts are demonstrated by Actavis's substantial effort in tracking the habits of individual County physicians prescribing Kadian, and by the direct evidence of Actavis detailing County prescribers.

350. Actavis tracked, in substantial detail, the prescribing behavior of Lorain area physicians.

2. Cephalon

351. At the heart of Cephalon's deceptive promotional efforts was a concerted and sustained effort to expand the market for its branded opioids, Actiq and Fentora, far beyond their FDA-approved use in opioid-tolerant cancer patients. Trading on their rapid-onset formulation, Cephalon touted its opioids as the answer to "breakthrough pain"—a term its own KOL allies planted in the medical literature—whether cancer pain or not. Cephalon promoted this message through its sales force, paid physician speakers, advertisements, and CMEs, even after the FDA issued the company warnings and rejected an expanded drug indication.

352. Even as it promoted Actiq and Fentora off-label, Cephalon also purveyed many of the deceptive messages described above. It did so both directly—through detailing visits and speaker programs—and through the publications and CMEs of its third-party partners. These messages included misleading claims about functional improvement, addiction risk, pseudoaddiction, and the safety of alternatives to opioids.

353. Based on the highly coordinated and uniform nature of Cephalon's marketing, Cephalon conveyed these deceptive messages to Lorain prescribers. The materials that Cephalon generated in collaboration with third-parties were also distributed or made available in Lorain . Cephalon distributed these messages, or facilitated their distribution, in Lorain with the intent that Parm prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Cephalon's Deceptive Direct Marketing

354. Like the other Defendants, Cephalon directly engaged in misleading and deceptive marketing of its opioids through its sales force and branded advertisements. These messages were centrally formulated and intended to reach prescribers nationwide, including those practicing in the Lorain area. Cephalon also spent the money necessary to aggressively promote its opioid drugs, setting aside $20 million to market Fentora in 2009 alone.

i. *Cephalon's Fraudulent Off-Label Marketing of Actiq and Fentora*

355. Chief among Cephalon's direct marketing efforts was its campaign to deceptively promote its opioids for off-label uses. Cephalon reaps significant revenue from selling its opioids for treatment of chronic non-cancer pain. However, neither of its two opioid drugs— Actiq or Fentora—is approved for this purpose. Instead, both have indications that are very clearly and narrowly defined to limit their use to a particular form of cancer pain. Despite this restriction, and in order to claim its piece of the broader chronic non-cancer pain market, Cephalon deceptively and unlawfully marketed

Actiq and then Fentora for patients and uses for which they were not safe, effective, or allowed. This resulted in prescriptions written and paid and, grievously, caused patients to be injured and die. Cephalon's efforts to expand the market for its drugs beyond cancer pain extended to Lorain prescribers.

a) Cephalon launched its fraudulent marketing scheme for Actiq

356. Cephalon's Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate."[119]

357. Actiq is appropriately used only to treat "breakthrough" cancer pain that cannot be controlled by other medications. Breakthrough pain is a short-term flare of moderate-to- severe pain in patients with otherwise stable persistent pain. Actiq is a rapid-onset drug that takes effect within 10-15 minutes but lasts only a short time. It is also an extremely strong drug, considered to be at least 80 times more powerful than morphine. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients. Actiq is not safe in any dose for patients who are not opioid tolerant, meaning patients who have taken specific doses of opioids for a week or longer and whose systems have acclimated to the drugs.

358. In 1998, the FDA approved Actiq "***ONLY*** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[120] (emphasis in FDA document). Because of Actiq's dangers, wider, off-label uses—as the FDA label makes clear—are not permitted:

> This product ***must not*** be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic

[119] *See* John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs*, Wall St. J., Nov. 3, 2006.
[120] FDA Approval Letter for NDA 20-747 (Nov. 4, 1998) at 5, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.

> regimen of opioids. For this reason, ACTIQ is contraindicated in the management of acute or postoperative pain.[121]

359. Actiq and Fentora are thus intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain. Unlike other drugs, of which off-label uses are permitted but cannot be promoted by the drug maker, Actiq and Fentora are so potent that off- label use for opioid naïve patients is barred by the FDA, as their labels make clear.

360. Notwithstanding the drug's extreme potency and related dangers, and the FDA's explicit limitations, Cephalon actively promoted Actiq for chronic non-cancer pain—an unapproved, off-label use. Cephalon marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports-related injuries, and other conditions not associated with cancer and for which it was not approved, appropriate, or safe.

361. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its limited patient population. But by 2005, Actiq sales reached $412 million, making it Cephalon's second-highest selling drug. As a result of Cephalon's deceptive, unlawful marketing, sales exceeded $500 million by 2006.

b) October 1, 2006 – Cephalon fraudulently marked Actiq's successor drug, Fentora

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

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

administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth.

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

> Fatal respiratory depression has occurred in patients treated with FENTORA, including following use in opioid non-tolerant patients and improper dosing. The substitution of FENTORA for any other fentanyl product may result in fatal overdose.
>
> Due to the risk of respiratory depression, FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.[122]

364. When Cephalon launched Fentora on October 1, 2006, it picked up the playbook it had developed for Actiq and simply substituted in Fentora. Cephalon immediately shifted 100 general pain sales representatives from selling Actiq to selling Fentora to the very same physicians for uses that would necessarily and predictably be off-label. Cephalon's marketing of Actiq therefore "primed the market" for Fentora. Cephalon had trained numerous KOLs to lead promotional programs for Fentora, typically including off-label uses for the drug. Cephalon billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally—not breakthrough cancer pain in particular—from Actiq. Cephalon also developed a plan in 2007 to target elderly chronic pain patients via a multi-County tour with stops at AARP events, YMCAs, and senior living facilities.

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

365. On February 12, 2007, only four months after the launch, Cephalon CEO Frank Baldino told investors:

> [W]e've been extremely pleased to retain a substantial portion, roughly 75% of the ` rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come.[123]

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

> The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain. . . .
> . . . .
>
> We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication. . . . [opioids are] widely used in the treatment of. . . non-cancer patients . . . .
> . . . .
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and

[123] *See Cephalon Q4 2006 Earnings Call Transcript,* Seeking Alpha (February 12, 2007, 8:48 PM EST) at 5, http://seekingalpha.com/article/26813-cephalon-q4-2006-earnings-call-transcript.

> continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[124]

c) September 2007 – Reports of death and serious side effects led the FDA to issue a public health warning for Fentora

367. On September 10, 2007, Cephalon sent letters to doctors warning of deaths and other "serious adverse events" connected with the use of Fentora, indicating that "[t]hese deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients), improper dosing, and/or improper product substitution."[125] The warning did not mention Cephalon's deliberate role in the "improper patient selection."

368. Two weeks later, the FDA issued its own Public Health Advisory. The FDA emphasized, once again, that Fentora should be prescribed only for approved conditions and that dose guidelines should be carefully followed. The FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label uses. The FDA Advisory warned that Fentora should not be used for any off-label conditions, including migraines, post-operative pain, or pain due to injury, and that it should be given only to patients who have developed opioid tolerance. The Advisory reiterated that, because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.[126]

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

[125] Letter from Jeffrey M. Dayno, M.D., Vice President, Medical Services, Cephalon, Inc. to Healthcare Providers (Sept. 10, 2007), http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMed icalProducts/UCM154439.pdf.

[126] FDA Public Health Advisory, *Important Information for the Safe Use of Fentora (fentanyl buccal tablets*) (Sept. 26, 2007), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.

369. Notwithstanding the regulatory scrutiny, Cephalon's off-label marketing continued. Cephalon's 2008 internal audit of its Sales & Marketing Compliance Programs concluded that marketing and tactical documents, as written, may be construed to promote off-label uses. The same report acknowledged that Cephalon lacked a process to confirm that speakers' program participants were following Cephalon's written, formal policies prohibiting off-label promotion, and that "non-compliant [Cephalon Speaker Programs] may be taking place." Moreover, the report acknowledged that Cephalon's "call universe" may include "inappropriate prescribers"— prescribers who had nothing to do with cancer pain.

d) May 6, 2008 – The FDA rejected Cephalon's request for expanded approval of Fentora

370. Cephalon filed a supplemental new drug application, ("sNDA"), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. Cephalon admitted that Fentora already had been heavily prescribed for non-cancer pain, but argued that such widespread use demonstrated why Fentora should be approved for these wider uses.[127] Cephalon's application also conceded that "[t]o date, no medication has been systematically evaluated in clinical studies or approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain." *Id.*

371. In response to Cephalon's application, the FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.[128] By a vote of 17-3, the relevant Advisory Committee—a panel of outside experts—voted against recommending approval of Cephalon's sNDA

[127] *See Fentora CII: Advisory Committee Briefing Document,* U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf.

[128] *See* Yoo Jung Chang & Lauren Lee, *Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System ("AERS") Database*, U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDAcorepresentations.ppt#289,1 (last visited May 17, 2017).

for Fentora, citing the potential harm from broader use. On September 15, 2008, the FDA denied Cephalon's application and requested, in light of Fentora's already off- label use, that Cephalon implement and demonstrate the effectiveness of proposed enhancements to Fentora's Risk Management Program. In December 2008, the FDA followed that request with a formal request directing Cephalon to submit a Risk Evaluation and Mitigation Strategy for Fentora.

e) March 26, 2009 – the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") warned Cephalon about its misleading advertising of Fentora

372. Undeterred by the rejection of its sNDA, Cephalon continued to use its general pain sales force to promote Fentora off-label to pain specialists as an upgrade of Actiq for the treatment of non-cancer breakthrough pain. Deceptively and especially dangerously, Cephalon also continued to promote Fentora for use by all cancer patients suffering breakthrough cancer pain, and not only those who were opioid tolerant.

373. On March 26, 2009, DDMAC issued a Warning Letter to Cephalon, telling Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug.[129] Specifically, the Warning Letter asserted that a sponsored link on Google and other search engines for Fentora, which said "[l]earn about treating breakthrough pain in patients with cancer,"[130] was improper because it "misleadingly broaden[ed] the indication for Fentora by implying that any patient

[129] Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (March 26, 2009), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166238.pdf.

[130] Screen shots of the sponsored link are available here: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166240.pdf.

with cancer who requires treatment for breakthrough pain is a candidate for Fentora therapy . . . when this is not the case."

374. DDMAC emphasized that Fentora's label was limited to cancer patients with breakthrough pain **"*who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.*"** (emphasis in original). DDMAC explained that the advertisement was "especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original). DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate **any** risk information associated with the use" of the drug. (emphasis in original).

f) Cephalon continues to knowingly, deceptively, and illegally promote Fenotra for off-label uses

375. Cephalon's own market research studies confirm that its Fentora promotions were not focused on physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat

oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

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

377. Cephalon was also aware that its detailing had an impact on prescription rates.

378. In 2011, Cephalon wrote and copyrighted an article titled "2011 Special Report: An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA®) and Oral Transmucosal Fentanyl Citrate (ACTIQ®)" that was published in *Pain Medicine News*.[131] The article promoted Cephalon's drugs for off-label uses by stating that the "judicious use of opioids can facilitate effective and safe management of chronic pain" and noted that Fentora "has been shown to be effective in treatment of [break through pain] associated with multiple causes of pain," not just cancer.[132]

ii. *Cephalon's Misrepresentation of the Risks Associateed with the Use of Opioids for the Long-Term Treatment of Chronic Pain*

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

380. There is no scientific evidence corroborating a link between chronic opioid therapy and increased functionality. Any suggestion of such a link is, in fact, false.

381. Along with deploying its sales representatives, Cephalon used speakers bureaus to help reach prescribers. The company viewed each treating physician as a vehicle to generate prescriptions – whether written by that physician directly or caused indirectly by his or her influence over other physicians.

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[131] http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems (accessed May 30, 2017)
[132] *Id.*

382. Having determined that speakers were an effective way to reach prescribers, Cephalon set to work ensuring that its speakers would disseminate its misleading messages. Cephalon did not disclose to speakers that, even when these tools are applied, they are unable to control for the risk of addiction.

383. As with the other Defendants, Cephalon deployed the made-up concept of "pseudoaddiction" to encourage prescribers to address addictive behavior in the worst way possible—with more opioids.

384. Working with FSMB, Cephalon also trained its speakers to turn doctors' fear of discipline on its head—doctors, who believed 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 pain. Through this messaging, Cephalon aimed to normalize the prescribing of opioids for chronic pain and failed to acknowledge the serious risks of long-term opioid use and its inappropriateness as a front-line treatment for pain.

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

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386. The misleading messages and materials Cephalon provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and alternatives. This deception was national in scope and included Lorain . Cephalon's nationwide messages have reached Lorain prescribers in a number of ways; tthey were delivered by Cephalon's sales representatives in

detailing visits and made available to County patients and prescribers through websites and ads, including ads in prominent medical journals. They have also been delivered to County prescribers by Cephalon's paid speakers, who were required by Cephalon policy to stay true to the company's nationwide messaging.

b. Cephalon's Deceptive Third-Party Statements

387. Like the other Defendants, Cephalon also relied on third parties to disseminate its messages through deceptive publications and presentations. By funding, developing and reviewing the content, and distributing and facilitating the distribution of these messages, Cephalon exercised editorial control over them. Cephalon, in some instances, used its sales force to directly distribute certain publications by these Front Groups and KOLs, rendering those publications "labeling" within the meaning of § 21 C.F.R. § 1.3(a) and making Cephalon responsible for their contents. Cephalon also deployed its KOLs as speakers for talks and CMEs to selected groups of prescribers.

388. Cephalon's relationships with several such Front Groups and KOLs—and the misleading and deceptive publications and presentations those relationships generated—are described below.

i. *FSMB – Responsible Opioid Prescribing*

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

390. *Responsible Opioid Prescribing* was a signature piece of Dr. Fishman's work and contained a number of deceptive statements. This publication claimed that, because pain had a negative impact

on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.

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

392. Cephalon spent $150,000 to purchase copies of *Responsible Opioid Prescribing* in bulk. It then used its sales force to distribute these copies to 10,000 prescribers and 5,000 pharmacists nationwide. These were available to, and intended to, reach prescribers and pharmacists in Lorain .

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

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

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

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

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

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

398. Starting in 2007, Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain.*[133] It is rife with misrepresentations regarding the risks, benefits, and superiority of opioids.

399. For example, *Treatment Options* deceptively asserts that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids "give [pain patients] a quality of life [they] deserve." There is no scientific evidence

[133] https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (accessed May 30, 2017)

corroborating that statement, and such statements are, in fact, false. Available data demonstrate that patients on chronic opioid therapy are actually *less likely* to participate in life activities like work.

400. *Treatment Options* also claims that addiction is rare and is evident from patients' conduct in self-escalating their doses, seeking opioids from multiple doctors, or stealing the drugs. *Treatment Options* further minimizes the risk of addiction by claiming that it can be avoided through the use of screening tools, like "opioid agreements," which can "ensure [that patients] take the opioid as prescribed." Nowhere does *Treatment Options* explain to patients and prescribers that neither "opioid agreements" nor any other screening tools have been scientifically validated to decrease the risks of addiction, and the publication's assurances to the contrary are false and deceptive.

401. *Treatment Options* also promotes the use of opioids to treat chronic pain by painting a misleading picture of the risks of alternate treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses, and attributes 10,000 to 20,000 deaths a year annually to NSAID overdose. According to *Treatment Options*, NSAIDs are different from opioids because opioids have "no ceiling dose," which is beneficial since some patients "need" larger doses of painkillers than they are currently prescribed. These claims misleadingly suggest that opioids are safe even at high doses and omit important information regarding the risks of high-dose opioids.

402. Additionally, *Treatment Options* warns that the risks associated with NSAID use increase if NSAIDs are "taken for more than a period of months," but deceptively omits any similar warning about the risks associated with the long-term use of opioids. This presentation paints a misleading picture of the risks and benefits of opioid compared with alternate treatments.

403. APF distributed 17,200 copies of *Treatment Options* in 2007 alone. It is currently available online and was intended to reach Lorain prescribers and pharmacists.

iii. *Key Opinion Leaders and Misleading Science*

404. Cephalon also knew that its misleading messages would be more likely to be believed by prescribers if they were corroborated by seemingly neutral scientific support.

405. Employing these tactics, Cephalon caused the term "breakthrough pain"—a term it seeded in the medical literature—to be used in articles published by practitioners and clinicians it supported. With funding from Cephalon, for example, Dr. Portenoy wrote an article that purported to expand the definition of breakthrough cancer pain to non-cancer indications, vastly expanding the marketing potential of Cephalon's Fentora. The article was published in the nationally circulated *Journal of Pain* in 2006 and helped drive a surge in Fentora prescriptions.

406. The concept of "breakthrough pain" ultimately formed the sole basis for the central theme of promotional messages Cephalon cited to support the approval and marketing of Actiq and Fentora, rapid-acting opioids which begin to work very quickly but last only briefly. Neither of these drugs had a natural place in the treatment of chronic pain before Cephalon's marketing campaign changed medical practice. A recent literature survey of articles describing non-cancer breakthrough pain calls into question the validity of the concept, suggesting it is not a distinct pain condition but a hypothesis to justify greater dosing of opioids. In other words, Cephalon conjured the science of breakthrough pain in order to sell its drugs.

407. As one scholar has pointed out, references to breakthrough pain in articles published on the MEDLINE bibliographic database spiked in 1998 and again in 2006.[134] These spikes coincide with FDA's approval of Actiq and Fentora.

[134] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut , Georgetown U. Med. Ctr. (June 25, 2010), *available at* pharmedout.galacticrealms.com/Fugh BermanPrescriptionforConflict6-25-10.pdf. (accessed date)

iv. *Misleading Continuing Medical Education*

408. Cephalon developed sophisticated plans for the deployment of its KOLs, broken down by sub-type and specialty, to reach targeted groups of prescribers through CMEs. Cephalon used the CME programs it sponsored to deceptively portray the risks related to the use of opioids to treat chronic non-cancer pain and promote the off-label use of Actiq and Fentora.

409. In 2007 and 2008, Cephalon sponsored three CMEs that each positioned Actiq and Fentora as the only "rapid onset opioids" that would provide effective analgesia within the time period during which "breakthrough pain" was at its peak intensity. Although the CMEs used only the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME knew it referred only to Actiq or Fentora.

410. The CMEs each taught attendees that there was no sound basis for the distinction between cancer and non-cancer "breakthrough pain," and one instructed patients that Actiq and Fentora were commonly used in non-cancer patients, thus effectively endorsing this use. Optimizing Opioid Treatment for Breakthrough Pain, offered online by Medscape, LLC from September 28, 2007, through December 15, 2008, was prepared by KOL Dr. Webster and M. Beth Dove. It recommends prescribing a "short-acting opioid" (e.g., morphine, hydromorphone, oxycodone) "when pain can be anticipated," or a rapid-onset opioid when it cannot. The only examples of rapid-onset opioids then on the market were oral transmucosal fentanyl citrate (i.e., Actiq) or fentanyl effervescent buccal tablet (i.e., Fentora): "Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients and are frequently prescribed to treat [breakthrough pain] in noncancer patients as well."

411. Optimizing Opioid Treatment for Breakthrough Pain not only deceptively promoted Cephalon's drugs for off-label use, but also misleadingly portrayed the risks, benefits, and superiority of opioids for the treatment of chronic pain. For example, the CME misrepresented that Actiq and Fentora would help patients regain functionality by advising that they improve patients' quality of life

and allow for more activities when taken in conjunction with long-acting opioids. The CME also minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids.

412. Around the same time, Dr. Webster was receiving nearly $2 million in funding from Cephalon.

413. Optimizing Opioid Treatment for Breakthrough Pain was available online and was intended to reach County prescribers.

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

415. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski and Michael J. Brennan, M.D. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009.[135] It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommended dispensing "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," *i.e.*,

[135] https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain (accessed May 30, 2017)

Actiq, and "fentanyl buccal tablet," *i.e.*, Fentora, including in patients with chronic non-cancer pain. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on Cephalon's speakers bureau.[136] Dr. Fine also received funding from Cephalon for consulting services.

416. *Opioid-Based Management of Persistent and Breakthrough Pain* was available to and was intended to reach County prescribers.

417. Cephalon's control over the content of these CMEs is apparent based on its advance knowledge of their content. A December 2005 Cephalon launch plan set forth key "supporting messages" to position Fentora for its product launch. Among them was the proposition that "15-minute onset of action addresses the unpredictable urgency of [breakthrough pain]." Years later, the same marketing messages reappeared in the Cephalon-sponsored CMEs described above. Echoing the Cephalon launch plan, Optimizing Opioid Treatment for Breakthrough Pain stated that "[t]he unpredictability of [breakthrough pain] will strongly influence the choice of treatment" and that Fentora "delivers an onset of analgesia that is similar to [Actiq] at ≤ 15 minutes." Similarly, Opioid-Based Management of Persistent and Breakthrough Pain defined "breakthrough pain" as "unpredictable," over a table describing both cancer and non-cancer "breakthrough pain."

418. Cephalon tracked the effectiveness of its deceptive marketing through third parties, demonstrating that Cephalon not only planned for, but depended upon, their activities as a key element of its marketing strategy. These programs were available to prescribers in Lorain and, based on the uniform and nationwide character of Cephalon's marketing featured the same deceptive messages described above.

[136] 14 of 21 panel members who drafted the AAPM/APS Guidelines received support from Janssen, Cephalon, Endo, and Purdue.

c. Cephalon's Deceptive Third-Party Statements to County Prescribers and Patients

419. Cephalon used various measures to disseminate its deceptive statements regarding the risks of off-label use of Actiq and Fentora and the risks, benefits, and superiority of opioids to County patients and prescribers.

420. Cephalon's speakers regularly held talks for County prescribers. These talks followed the same deceptive talking points covered in Cephalon's speakers' training.

421. Cephalon also targeted County prescribers through the use of its sales force.

422. Given that Cephalon's own studies demonstrated that the overwhelming majority of oncologists diagnose and treat breakthrough cancer pain themselves, Cephalon knew the only purpose of representatives meeting with these prescribers was to promote off-label use. Based on the uniform and nationwide character of Cephalon's marketing, Cephalon's deceptive messages would have been disseminated to County prescribers by Cephalon's sales representatives during these events.

423. Sales representatives, and the misrepresentations on which they were trained, drove significant Fentora sales.

3. Endo

424. Endo promoted its opioids through the full array of marketing channels. The company deployed its sales representatives, paid physician speakers, journal supplements, and advertising in support of its branded opioids, principally Opana and Opana ER. Misleading claims about the purportedly lower abuse potential of Opana ER featured prominently in this campaign. Endo also made many other deceptive statements and omissions. These included deceptive messages about functional improvement, addiction risk, "pseudoaddiction," addiction screening tools, and the safety of alternatives to opioids.

425. At the same time, Endo also relied on third-party partners to promote the safety, efficacy, and superiority of opioids generally, through a combination of CMEs, websites, patient

education pamphlets, and other publications. These materials echoed the misrepresentations described above, and also made deceptive statements about withdrawal symptoms and the safety of opioids at higher doses.

426. Through the highly coordinated and uniform nature of Endo's marketing, Endo conveyed these deceptive messages to County prescribers. The materials that Endo generated in collaboration with third-parties also were distributed or made available in Lorain . Endo distributed these messages, or facilitated their distribution, in Lorain with the intent that County prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Endo's Deceptive Direct Marketing

427. Like the other Defendants, Endo used deceptive direct marketing to increase the sales of its dangerous opioids. As set forth below, Endo conveyed these deceptive messages in training of its sales force and recruited speakers, who in turn conveyed them to physicians; in a misleading journal supplement; and in unbranded advertising.

i. *Endo's Sales Force and Deceptive Sales Training*

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

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

430. Endo specifically directed its sales force to target physicians who would prescribe its drugs to treat chronic pain. For example, an Opana Brand Tactical Plan dated August, 2007 aimed to increase "Opana ER business from [the Primary Care Physician] community" more than 45% by the end of that year. Indeed, Endo sought to develop strategies that would be most persuasive to primary care doctors—strategies that sought to influence the prescribing behavior of primary care physicians through the use of subject matter experts. A February 2011 Final Report on Opana ER Growth Trends, for example, predicted that Endo's planned "[u]se of Pain Specialists as local thought leaders should affect increased primary care adoption."

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

432. Endo knew that its marketing reached physicians repeatedly because it tracked their exposure. Internal Endo documents dated August 23, 2006 demonstrate that the following percentages of physicians would view an Endo journal insert (or paid supplement) at least 3 times in an 8 month period: 86% of neurologists; 86% of rheumatologists; 85% of oncologists; 85% of anesthesiologists; 70% of targeted primary care physicians; and 76% of OB/GYNs.

433. Endo was not only able to reach physicians through its marketing, but also successfully impart its marketing messages. The company found that its promotional materials tripled prescribers' ability to recall the sales message and doubled their willingness to prescribe Opana ER in the future. This was true of marketing that contained deceptions.

434. For example, according to internal Endo documents, up to 10% of physicians it detailed were able to recall, without assistance, the message that Opana ER had "Minimal/less abuse/misuse" potential than other drugs. The Endo message that prescribers retained was a plain misrepresentation: that use of Opana ER was unlikely to lead to abuse and addiction. Although Opana ER always has been classified under Schedule II as a drug with a "high potential for abuse", the largest single perceived advantage of Opana ER, according to a survey of 187 physicians who reported familiarity with the drug, was "perceived low abuse potential," cited by 15% of doctors as an advantage. Low abuse potential was among the deceptive messages that County prescribers received, and retained, from Endo sales representatives.

435. Endo's own internal documents acknowledged the misleading nature of these statements, conceding that "Opana ER has an abuse liability similar to other opioid analgesics as stated in the [FDA-mandated] box warning." A September 2012 Opana ER Business Plan similarly stated that Endo needed a significant investment in clinical data to support comparative effectiveness, scientific exchange, benefits and unmet need, while citing lack of "head-to-head data" as a barrier to greater share acquisition.

436. Nevertheless, Endo knew that its marketing was extremely effective in turning physicians into prescribers. Nationally, the physicians Endo targeted for in-person marketing represented approximately 84% of all prescribers of Opana ER in the first quarter of 2010. Endo also observed that the prescribers its sales representatives visited wrote nearly three times as many prescriptions per month for Opana ER as those physicians who were not targeted for Endo's marketing—7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly 30 prescriptions per month. Internal Endo documents from May 2008 indicate that Endo expected that each of its sales representatives would generate 19.6

prescriptions per week by the end of 2008. As summarized by a February 2011 report on Opana ER growth trends, Endo's "[a]ggressive detailing [is] having an impact."

437. More broadly, Endo's sales trainings and marketing plans demonstrate that its sales force was trained to provide prescribers with misleading information regarding the risks of opioids when used to treat chronic pain. Foremost among these messages were misleading claims that the risks of addiction, diversion, and abuse associated with opioids—and Endo's products in particular—were low, and lower than other opioids.

a) Endo's Sales Force Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy.

438. By way of illustration, Endo's Opana ER INTAC Technology Extended-Release Sell Sheet Implementation Guide, which instructs Endo sales personnel how to effectively "support key messages" related to the marketing of Opana ER, states that it is an "approved message" for sales representatives to stress that Opana ER was "designed to be crush resistant," even though this internal document conceded that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER."

439. Other Endo documents acknowledged the limitations on Opana ER's INTAC technology, conceding that while Opana ER may be resistant to pulverization, it can still be "ground" and "cut into small pieces" by those looking to abuse the drug.

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

441. The only reason to promote the crush resistance of Opana ER was to persuade doctors that there was less risk of abuse, misuse, and diversion of the drug. The idea that Opana ER

was less addictive than other drugs was the precise message that County prescribers took from Endo's marketing.

442. On May 10, 2013 the FDA warned Endo that there was no evidence that Opana ER's design "would provide a reduction in oral, intranasal, or intravenous abuse" and that the post-marketing data Endo had submitted to the FDA "are insufficient to support any conclusion about the overall or route-specific rates of abuse." Even though it was rebuked by the FDA, Endo continued to market Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused.

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

444. Endo's sales training also misrepresented the risks of addiction associated with Endo's products by implying that Opana's prolonged absorption would make it less likely to lead to abuse. For example, a presentation titled "Deliver the Difference for the Opana Brand in POA II" sets out that one of the "[k]ey [m]essages" for the Endo sales force was that Opana ER provides "[s]table, steady-state plasma levels for true 12-hour dosing that lasts." Endo's sales representatives used this messaging to imply to County prescribers that Opana ER provided "steady state" pain relief, making Opana less likely to incite euphoria in patients and less likely to lead to addiction.

445. Endo further instructed its sales force to promote the misleading concept of "pseudoaddiction,"—i.e., that drug-seeking behavior was not cause for alarm, but merely a manifestation of undertreated pain. In a sales training document titled "Understanding the Primary Care MD and their use of Opioids," Endo noted that the "biggest concerns" among primary care physicians were "prescription drug abuse (84.2%), addiction (74.9%), adverse effects (68%), tolerance (60.7%), and medication interaction (32%)." In response to these concerns, Endo instructed its sales representatives to ask whether their customers were "confus[ing] 'pseudo-addiction' with 'drug-seekers'" and how confident they were that their health care providers "know these differences (Tolerance, Dependence, Addiction, Pseudo- Addiction . . .)."

b) Endo's Sales Force Deceptively Implied that Chronic Opioid Therapy Would Improve Patients' Ability to Function.

446. In addition to their deceptive messages regarding addiction, Endo's promotional materials and sales trainings also misleadingly claimed that patients using opioids for the long- term treatment of chronic pain would experience improvements in their daily function. In reality, long-term opioid use has not been shown to, and does not, improve patients' function, and, in fact, is often accompanied by serious side effects that degrade function. Endo's own internal documents acknowledged that claims about improved quality of life were unsubstantiated "off label claims."

447. Nevertheless, Endo distributed product advertisements that suggested that using Opana ER to treat chronic pain would allow patients to perform demanding tasks like work as a chef. One such advertisement states prominently on the front: "Janice is a 46-year-old chef with chronic low back pain. She needs a treatment option with true 12-hour dosing." The advertisement does not mention the "moderate to severe pain" qualification in Opana ER's indication, except in the fine print. These advertisements were mailed to prescribers and distributed by Endo's sales force in detailing visits, which would have included Endo representatives' visits to prescribers.

448. In a 2007 Sales Tool that was intended to be shown by Endo sales personnel to physicians during their detailing visits, Endo highlighted a hypothetical patient named "Bill," a 40-year-old construction worker who was reported to suffer from chronic low back pain. According to the Sales Tool, Opana ER will make it more likely that Bill can return to work and support his family.

449. Similarly, training materials for sales representatives from March 2009 ask whether it is true or false that "[t]he side effects of opioids prevent a person from functioning and can cause more suffering than the pain itself." The materials indicate that this is "[f]alse" because "[t]he overall effect of treatment with opioids is very favorable in most cases."

450. A sales training video dated March 8, 2012 that Endo produced and used to train its sales force makes the same types of claims. A patient named Jeffery explains in the video that he suffers from chronic pain and that "chronic pain [. . .] reduces your functional level." Jeffery claims that after taking Opana ER, he "can go out and do things" like attend his son's basketball game and "[t]here's no substitute for that." This video was shown to Endo's sales force, which adopted its misleading messaging in its nationwide sales approach, including the approach it used in Lorain .

451. Claims of improved functionality were central to Endo's marketing efforts for years. A 2012 Endo Business Plan lists ways to position Opana ER, and among them is the claim that Opana ER will help patients "[m]aintain[] normal functionality, sleep, [and] work/life/performance productivity" and have a positive "[e]ffect on social relationships." Indeed, that business plan describes the "Opana ER Vision" as "[t]o make the Opana franchise (Opana ER, Opana, Opana Injection) the choice that maximizes improvement in functionality and freedom from the burden of moderate-to-severe pain."

c) Endo's Sales Force Deceptively presented the Risks and Benefits of Opioids to Make Them Appear Safer Than Other Analgesics

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

453. Endo distributed *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* to 116,000 prescribers in 2007, including primary care physicians.

ii. *Endo's Speakers Bureau Programs Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy*

454. In addition to its sales representatives' visits to doctors, Endo also used deceptive science and speaker programs to spread its deceptive messages.

455. Endo leaned heavily on its speakers' bureau programs. In 2008 alone, Endo spent nearly $4 million to promote up to 1,000 speakers programs around the country. Endo contracted with a medical communications firm to operate its speakers bureau program, planning to hold a total of 500 "fee-for-service . . . peer-to-peer promotional programs" for Opana ER in just the second half of 2011, including dinners, lunches and breakfasts. These programs were attended by sales representatives, revealing their true purpose as marketing, rather than educational, events.

456. Endo's internal reporting stated that the "return on investment" turned positive 8-12 weeks after such programs. Endo measured that return on investment in numbers of prescriptions

written by physicians who attended the events. One internal Endo document concluded: "[w]e looked at the data for [the] 2011 program and the results were absolutely clear: physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than they had before they participated. You can't argue with results like that."

457. These speakers bureau presentations included the very same misrepresentations Endo disseminated through its sales representatives. A 2012 speaker slide deck for Opana ER— on which Endo's recruited speakers were trained and to which they were required to adhere to in their presentations—misrepresented that the drug had low abuse potential, in addition to suggesting that as many as one-quarter of the adult population could be candidates for opioid therapy.

458. In addition, a 2013 training module directed speakers to instruct prescribers that "OPANA ER with INTAC is the only oxymorphone designed to be crush resistant" and advised that "[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush resistant is to prescribe OPANA ER with INTAC." This was a key point in distinguishing Opana ER from competitor drugs. Although Endo mentioned that generic versions of oxymorphone were available, it instructed speakers to stress that "[t]he generics are not designed to be crush resistant." This was particularly deceptive given that Opana ER was not actually crush-resistant.

459. In 2009, Endo wrote a talk titled *The Role of Opana ER in the Management of Chronic Pain*. The talk included a slide titled "Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain," which cited the AAPM/APS Guidelines—and their accompanying misstatements regarding the likelihood of addiction (by claiming that addiction risks were manageable regardless of patients' past abuse histories) while omitting their disclaimer regarding the lack of supporting evidence in favor of that position. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

460. The misleading messages and materials Endo provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Lorain . Endo's nationwide messages would have reached County prescribers in a number of ways. For example, they were carried into Lorain by Endo's sales representatives during detailing visits as well as made available to County patients and prescribers through websites and ads. They also have been delivered to County prescribers by Endo's paid speakers, who were required by Endo policy and by FDA regulations to stay true to Endo's nationwide messaging.

iii. *Endo's Misleading Journal Supplement*

461. In 2007, Endo commissioned the writing, and paid for the publishing of a supplement available for CME credit in the Journal of Family Practice called Pain Management Dilemmas in Primary Care: Use of Opioids, and it deceptively minimized the risk of addiction by emphasizing the effectiveness of screening tools. Specifically, it recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain. It also falsely claimed that, through the use of tools like toxicology screens, pill counts, and a "maximally structured approach," even patients at high risk of addiction could safely receive chronic opioid therapy. Endo distributed 96,000 copies of this CME nationwide, and it was available to, and was intended to, reach County prescribers.

iv. *Endo's Deceptive Unbranded Advertising*

462. Endo also used unbranded advertisements to advance its goals. By electing to focus on unbranded marketing, Endo was able to make claims about the benefits of its opioids that the FDA would never allow in its branded materials. The chart below compares an Endo unbranded statement with one of Endo's FDA-regulated, branded statements:

Living with Someone with Chronic Pain (2009)(Unbranded)	**Opana ER Advertisement (2011/2012/2013) (Branded)**
Patient education material created by Endo	Endo advertisement
"Most health care providers who treat people with pain agree that **most people do not develop an addiction problem**."	"[C]ontains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit." "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

b. Endo's Deceptive Third-Party Statements

463. Endo's Efforts were not limited to directly making misrepresentations through its marketing materials, its speakers, and its sales force. Endo believed that support for patient advocacy and professional organizations would reinforce Endo's position as "the pain management company."

464. Prior to, but in contemplation of, the 2006 launch of Opana ER, Endo developed a "Public Stakeholder Strategy." Endo identified "tier one" advocates to assist in promoting the approval and acceptance of its new extended release opioid. Endo also intended to enlist the support of organizations that would be "favorable" to schedule II opioids from a sales perspective and that engaged in, or had the potential to advocate for, public policy. Endo sought to develop its relationships with these organizations through its funding. In 2008, Endo spent $1 million per year to attend conventions of these pro-opioid medical societies, including meetings of AAPM, APS, and the American Society of Pain Management Nursing ("ASPMN").

465. APF's ability to influence professional societies and other third parties is demonstrated by its approach to responding to a citizens' petition filed with the FDA by the Physicians for Responsible Opioid Prescribing (the "PROP Petition"). The PROP petition, filed by a group of prescribers who had become concerned with the rampant prescribing of opioids to treat chronic pain, asked the FDA to require dose and duration limitations on opioid use and to change the wording of the approved indication of various long-acting opioids to focus on the severity of the pain they are intended to treat.

466. The PROP Petition set off a flurry of activity at Endo. It was understood that Endo would respond to the petition but Endo personnel wondered "[s]hould we [. . .] consider filing a direct response to this [citizens' petition] or do you think we are better served by working through our professional society affiliations?" One Endo employee responded: "My sense is the societies are better placed to make a medical case than Endo." Endo's Director of Medical Science agreed that "a reply from an external source would be most impactful." These communications reflected Endo's absolute confidence that the professional societies would support its position.

i. *APF*

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

468. Endo's influence over APF's activities was so pervasive that APF President Will Rowe reached out to Defendants—including Endo—rather than his own staff, to identify potential

authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine. Personnel from Defendants Purdue, Endo, Janssen, and Cephalon worked with Rowe to formulate APF's response which was ultimately published.

469. Documents also indicate that Endo personnel were given advance notice of the materials APF planned to publish on its website and provided an opportunity to comment on the content of those materials before they were published. For example, in early July of 2009, APF's Director of Strategic Development wrote to Endo personnel to give them advance notice of content that APF planned to be "putting . . . up on the website but it's not up yet." The Endo employee assured the sender that she "w[ould] not forward it to anyone at all" and promised that she would "'double delete it' from [her] inbox." In response, APF's Director of Strategic Development replied internally with only four words: "And where's the money?"

470. At no time was Endo's relationship with APF closer than during its sponsorship of the NIPC. Before being taken over by APF, the NIPC was sponsored by Professional Postgraduate Services which the Accreditation Council for Continuing Medical Education determined to be a "commercial interest" and could no longer serve as a sponsor. In response, Endo reached out to APF. An August 2009 document titled "A Proposal for the American Pain Foundation to Assume Sponsorship of the National Initiative on Pain Control," pointed out that "[f]or the past 9 years, the NIPC has been supported by unrestricted annual grants from Endo Pharmaceuticals, Inc." According to this document, APF's sponsorship of the NIPC "[o]ffers the APF a likely opportunity to generate new revenue, as Endo has earmarked substantial funding: $1.2 million in net revenue for 2010 to continue the NIPC." Further, sponsorship of the APF would "[p]rovide[] numerous synergies to disseminate patient education materials," including "[h]andouts to attendees at all live events to encourage physicians to drive their patients to a trusted source for pain education—the APF website."

471. A September 14, 2009 presentation to APF's board contained a materially similar discussion of NIPC sponsorship, emphasizing the financial benefit to APF from assuming the role of administering NIPC. The proposal "offer[ed] a solution to continue the development and implementation of the NIPC initiative as non-certified . . . yet independent education to physicians and healthcare professionals in the primary care setting, while providing the APF with a dependable, ongoing source of grant revenue." A number of benefits related to NIPC sponsorship were listed, but chief among them was "a likely opportunity [for APF] to generate new revenue, as Endo has earmarked substantial funding: $1.2 million in net revenue for 2010 to continue the NIPC."

472. Internal Endo scheduling documents indicate that "NIPC module curriculum development, web posting, and live regional interactive workshops" were Endo promotional tasks in 2010. Endo emails indicate that Endo personnel reviewed the content created by NIPC and provided feedback.

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

474. From 2007 until at least 2011, Endo also meticulously tracked the distribution of NIPC materials, demonstrating Endo's commercial interest in, and access to, NIPC's reach. Endo knew exactly how many participants viewed NIPC webinars and workshops and visited its website, Painknowledge.com. Endo not only knew how many people viewed NIPC's content, but what their backgrounds were (e.g., primary care physicians or neurologists). Endo's access to and detailed understanding of the composition of the audience at these events demonstrates how deeply Endo

was involved in NIPC's activities. Moreover, Endo tracked the activities of NIPC—ostensibly a third party—just as it tracked its own commercial activity.

475. Endo worked diligently to ensure that the NIPC materials it helped to develop would have the broadest possible distribution. Endo's 2008 to 2012 Opana Brand Tactical Plan indicates that it sought to reach 1,000 prescribers in 2008 through live NIPC events, and also to "[l]everage live programs via enduring materials and web posting." Endo also planned to disseminate NIPC's work by distributing two accredited newsletters to 60,000 doctors nationwide for continuing education credit and by sponsoring a series of 18 NIPC regional case-based interactive workshops. Endo had earmarked more than one million dollars for NIPC activities in 2008 alone.

476. In short, NIPC was a key piece of Endo's marketing strategy. Indeed, internal APF emails question whether it was worthwhile for APF to continue operating NIPC given that NIPC's work was producing far more financial benefits for Endo than for APF. Specifically, after Endo approved a $244,337.40 grant request to APF to fund a series of NIPC eNewsletters, APF personnel viewed it as "[g]reat news," but cautioned that "the more I think about this whole thing, [Endo's] making a lot of money on this with still pretty slender margins on [APF's] end." APF's commitment to NIPC's "educational" mission did not figure at all in APF's consideration of the value of its work, and Endo's motive and benefit were never in doubt.

a) Misleading Medical Education

477. NIPC distributed a series of eNewsletter CMEs focused on "key topic[s] surrounding the use of opioid therapy" sponsored by Endo. These newsletters were edited by KOL Dr. Fine and listed several industry-backed KOLs, including Dr. Webster, as individual authors. Endo estimated that roughly 60,000 prescribers viewed each one. These CMEs were available to, and would have been accessed by, County prescribers. Before-and-after surveys, summarized in the chart below,

showed that prescriber comfort with prescribing opioids ranged from 27% to 62% before exposure to the CME, and from 76% to 92% afterwards:

Topic	Comfort level *prior to reading the article*	Comfort level *after reading the article*
Patient Selection and Initiation of Opioid Therapy as a Component of Pain Treatment	47%	87%
Informed Consent and Management Plans to Optimize Opioid Therapy for Chronic Pain	48%	81%
Risk Stratification and Evaluation of High-Risk Behaviors for Chronic Opioid Therapy	28%	76%
Integration of Nonpharmacologic and Multidisciplinary Therapies Into the Opioid Treatment Plan	42%	85%
Addressing Patients' Concerns Associated With Chronic Pain Treatment and Opioid Use	62%	92%
Opioid Therapy in Patients With a History of Substance Use Disorders	35%	85%
Urine Drug Testing: An Underused Tool	54%	86%
Appropriate Documentation of Opioid Therapy: The Emergence of the 4As and Trust and Verify as the Paradigm	44%	86%
Opioid Rotation	27%	92%
Discontinuing Opioid Therapy: Developing and Implementing an "Exit Strategy"	37%	90%

478. Endo documents made it clear that the persuasive power of NIPC speakers was directly proportional to their perceived objectivity. Accordingly, Endo personnel directed that, when giving Endo-sponsored talks, NIPC faculty would not appear to be "Endo Speakers." Nevertheless, the two parties understood that Endo and NIPC shared a common "mission to educate physicians" and working "through the APF . . . [wa]s a great way to work out . . .problems that could have been there without the APF's participation and support."

479. The materials made available on and through NIPC included misrepresentations. For example, Endo worked with NIPC to sponsor a series of CMEs titled *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult*. These CMEs misrepresented the prevalence of addiction by stating that opioids have "possibly less potential for abuse" in elderly patients than in younger patients, even though there is no evidence to support such an assertion. Moreover, whereas withdrawal symptoms

are always a factor in discontinuing long-term opioid therapy, *Persistent Pain in the Older Adult* also misleadingly indicated that such symptoms can be avoided entirely by tapering the patient's does by 10-20% per day for ten days. *Persistent Pain in the Older Patient*, for its part, made misleading claims that opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." NIPC webcast these CMEs from its own website, where they were available to, and were intended to reach, County prescribers.

b) Pain Knowledge

480. Working with NIPC enabled Endo to make a number of misleading statements through the NIPC's website, *Painknowledge.com*. Endo tracked visitors to *PainKnowledge.com* and used *Painknowledge.com* to broadcast notifications about additional NIPC programming that Endo helped to create.

481. APF made a grant request to Endo to create an online opioid "tool-kit" for NIPC and to promote NIPC's website, *Painknowledge.com*. In so doing, APF made clear that it planned to disseminate Defendants' misleading messaging. The grant request expressly indicated APF's intent to make misleading claims about functionality, noting: "Some of these people [in chronic pain] may be potential candidates for opioid analgesics, which can improve pain, function, and quality of life." Endo provided $747,517 to fund the project.

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

483. *Painknowledge.com* also deceptively minimized the risk of addiction by claiming that "[p]eople who take opioids as prescribed usually do not become addicted." *Painknowledge.com* did not

stop there. It deceptively portrayed opioids as safe at high doses and also misleadingly omitted serious risks, including the risks of addiction and death, from its description of the risks associated with the use of opioids to treat chronic pain.

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

c) *Exit Wounds*

485. Finally, Endo also sponsored APF's publication and distribution of *Exit Wounds*, a publication aimed at veterans that also contained a number of misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by Derek Mcginnis." Medical Writer X was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Medical Writer X's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

486. *Exit Wounds* is a textbook example of Medical Writer X's authorship on drug companies' behalf. The book misrepresented the functional benefits of opioids by stating that opioid medications "*increase* your level of functioning" (emphasis in original).

487. *Exit Wounds* also misrepresented that the risk of addiction associated with the use of opioids to treat chronic pain was low. It claimed that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."

488. Finally, *Exit Wounds* misrepresented the safety profile of using opioids to treat chronic pain by omitting key risks associated with their use. Specifically, it omitted warnings of the risk of interactions between opioids and benzodiazepines—a warning sufficiently important to be included

on Endo's FDA-required labels. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids—a particular risk for veterans.

489. As outlined above, Endo exercised dominance over APF and the projects it undertook in an effort to promote the use of opioids to treat chronic pain. In addition, as outlined above, Medical Writer X's work was being reviewed and approved by drug company representatives, motivating him to draft pro-opioid propaganda masquerading as science. Combined, these factors gave Endo considerable influence over the work of Medical Writer X and over APF. Further, by paying to distribute *Exit Wounds*, Endo endorsed and approved its contents.

ii. *Other Front Groups: FSMB, AAPM, and AGS*

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

491. In 2007, Endo sponsored FSMB's *Responsible Opioid Prescribing*, which in various ways deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* was drafted by "Dr. Fishman."

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

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

494. AGS's grant request to Endo made explicit reference to the CME that Endo was funding. Endo thus knew full well what content it was paying to distribute, and was in a position to evaluate that content to ensure it was accurate, substantiated, and balanced before deciding whether or not to invest in it. After having sponsored the AGS CME, Endo's internal documents indicate that Endo's pharmaceutical sales representatives discussed the AGS guidelines with doctors during individual sales visits.

495. Endo also worked with AAPM, which it viewed internally as "Industry Friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

496. A talk written by Endo in 2009 and approved by Endo's Medical Affairs Review Committee,[137] titled *The Role of Opana ER in the Management of Chronic Pain,* includes a slide titled *Use of*

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

Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain. That slide cites the AAPM/APS Guidelines, which contain a number of misstatements and omits their disclaimer regarding the lack of supporting evidence. This talk dangerously misrepresented to doctors the force and utility of the 2009 Guidelines. Furthermore, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

iii. *Key Opinion Leaders and Misleading Science*

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

498. Endo's 2010 publication plan for Opana ER identified a corporate goal of making Opana ER the second-leading branded product for the treatment of moderate-to-severe chronic pain (after OxyContin). Endo sought to achieve that goal by providing "clinical evidence for the use of Opana ER in chronic low back pain and osteoarthritis," and subsequently successfully had articles on this topic published.[138]

499. In the years that followed, Endo sponsored articles authored by Endo consultants and Endo employees, which argued that the metabolic pathways utilized by Opana ER, compared with other opioids, were less likely to result in drug interactions in elderly low back and osteoarthritis pain patients. In 2010, Endo directed its publication manager to reach out to a list of consultants

[138] These studies suffered from the limitations common to the opioid literature—and worse. None of the comparison trials lasted longer than three weeks. Endo also commissioned a six-month, open label trial during which a full quarter of the patients failed to find a stable dose, and 17% of patients discontinued, citing intolerable effects. In open label trials, subjects know which drug they are taking; such trials are not as rigorous as double-blind, controlled studies in which neither the patients nor the examiners know which drugs the patients are taking.

conducting an ongoing Endo-funded study, to assess their willingness to respond to an article[139] that Endo believed emphasized the risk of death from opioids, "without [] fair balance."[140]

500. Endo's reliance on flawed, biased research is also evident in its 2012 marketing materials and strategic plans. A 2012 Opana ER slide deck for Endo's speakers bureaus—on which these recruited physician speakers were trained and to which they were required to adhere—misrepresented that the drug had low abuse potential and suggested that as many as one-quarter of the adult population could be candidates for opioid therapy. Although the FDA requires such speaker slide decks to reflect a "fair balance" of information on benefits and risks, Endo's slides reflected one-sided and deeply biased information. The presentation's 28 literature citations were largely to "data on file" with the company, posters, and research funded by, or otherwise connected to, Endo. Endo's speakers relayed the information in these slides to audiences that were unaware of the skewed science on which the information was based.

501. A 2012 Opana ER Strategic Platform Review suffered from similar defects. Only a small number of the endnote referenced in the document, which it cited to indicate "no gap" in scientific evidence for particular claims, were to national-level journals. Many were published in lesser or dated journals, and written or directly financially supported by opioid manufacturers. Where the strategy document did cite independent, peer-reviewed research, it did so out of context. For example, it cited a 2008 review article on opioid efficacy for several claims, including that "treatment of chronic pain reduces pain and improves functionality," but it ignored the article's overall focus on the lack of consistent effectiveness of opioids in reducing pain and improving functional status.[141]

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

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

[141] Andrea M. Trescot et al., Opioids in the management of non-cancer pain: an Update of American Society of the Interventional Pain Physicians, Pain Physician 2008 Opioids Special Issue, 11:S5-S62.

502. Notwithstanding Endo's reliance upon dubious or cherry-picked science, in an Opana ER brand strategy plan it internally acknowledged the continuing need for a significant investment in clinical data to support comparative effectiveness. Endo also cited a lack of "head-to-head data" as a barrier to greater share acquisition, and the "lack of differentiation data" as a challenge to addressing the "#1 Key Issue" of product differentiation. This acknowledged lack of support did not stop Endo from directing its sales representatives to tell prescribers that its drugs were less likely to be abused or be addictive than other opioids.

503. Endo also worked with various KOLs to disseminate various misleading statements about chronic opioid therapy. For example, Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding your Pain: Taking Oral Opioid Analgesics*. This pamphlet deceptively minimized the risks of addiction by stating that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems," implying that patients who are taking opioids for pain are not at risk of addiction.

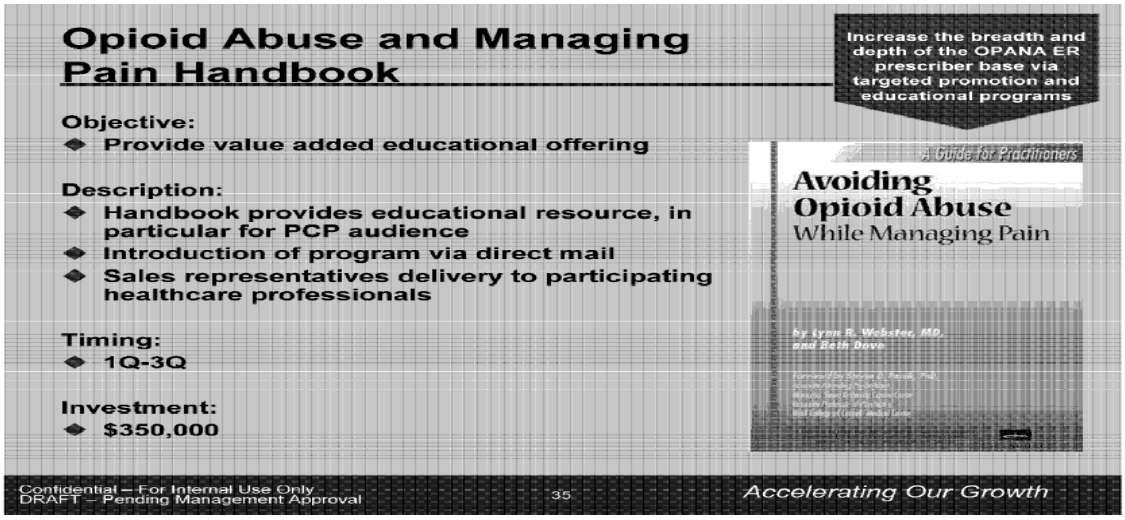
504. *Understanding your Pain: Taking Oral Opioid Analgesics* also misleadingly omitted any description of the increased risks posed by higher doses of opioid medication. Instead, in a Q&A format, the pamphlet asked "[i]f I take the opioid now, will it work later when I really need it?" and responded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

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

506. *Understanding Your Pain* was available on Endo's website during the time period of this Complaint and was intended to reach County prescribers.

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

508. A slide from an Opana ER business plan contemplated distribution of the book as part of Endo's efforts to "[i]ncrease the breadth and depth of the OPANA ER prescriber base via targeted promotion and educational programs." The slide indicates that the book would be particularly effective "for [the] PCP audience" and instructed "[s]ales representatives [to] deliver[the book] to participating health care professionals." The slide, shown below, demonstrates Endo's express incorporation of this book by a KOL into its marketing strategy:



509. Endo Documents indicate that, around 2007, the company purchased at least 50,000 copies of the book for distribution. Internal Endo documents Demonstrate that the book had been approved for distribution by Endo's sales force, and that Endo had fewer than 8,000 copies on hand in March of 2013. Based on the nationwide and uniform character of Endo's marketing, and the book's approval for distribution, this book was available to and was intended to reach prescribers.

c. Endo's Deceptive Statements to County Prescribers and Patients

510. Endo also directed the dissemination of the misstatements described above to County patients and prescribers, including through its sales force, speakers bureaus, CMEs, and the *Painknowledge.com* website.

511. Consistent with their training, Endo's sales representatives delivered all of these deceptive messages to County prescribers.

512. Endo also directed misleading marketing to County prescribers and patients through the APF/NIPC materials it sponsored, reviewed, and approved. For example, Endo hired a New York-based KOL to deliver a CME titled *Managing Persistent Pain in the Older Patient* on April 27, 2010. As described above, this CME misrepresented the prevalence of addiction in older patients and made misleading claims that chronic opioid therapy would improve patients' ability to function. An email invitation to the event and other NIPC programs was sent to "all healthcare professionals" in APF's database.

513. The significant response to *Painknowledge.com* also indicates that those websites were viewed by County prescribers, who were then exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids. As of September 14, 2010, *Painknowledge.com* had 10,426 registrants, 86,881 visits, 60,010 visitors, and 364,241 page views. Upon information and belief, based on the site's nationwide availability, among the site's visitors were County patients and prescribers who were then exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids.

514. Endo knew that the harms from its deceptive marketing would be felt in Lorain . It saw workers' compensation programs as a lucrative opportunity, and it promoted the use of opioids for chronic pain arising from work-related injuries, like chronic lower back pain. Endo developed

plans to "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss in those with pain; [with a] specific focus on high-risk employers and employees." In 2007, Endo planned to reach 5,000 workers' compensation carriers to ensure that Opana ER would be covered under disability insurance plans. Endo knew or should have known that claims for its opioids would be paid for by the County's workers' compensation program.

4. Janssen

515. Janssen promoted its branded opioids, including Duragesic, Nucynta, and Nucynta ER, through its sales representatives and a particularly active speakers program. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. Janssen also conveyed other misrepresentations including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

516. Janssen supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain. These materials likewise made deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments. They also claimed that opioid treatment would result in functional improvement, and further masked the risk of addiction by promoting the concept of pseudoaddiction.

517. Based on the highly coordinated and uniform nature of Janssen's marketing, Janssen conveyed these deceptive messages to County prescribers. The materials that Janssen generated in collaboration with third-parties also were distributed or made available in Lorain . Janssen distributed these messages, or facilitated their distribution, in Lorain with the intent that County prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Janssen's Deceptive Direct Marketing

518. Janssen joined the other Defendants in propagating deceptive branded marketing that falsely minimized the risks and overstated the benefits associated with the long-term use of opioids to treat chronic pain. Like the other Defendants, Janssen sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed identically across the country. These sales representatives were critical in transmitting Janssen's marketing strategies and talking points to individual prescribers. In 2011, at the peak of its effort to promote Nucynta ER, Janssen spent more than $90 million on detailing.

519. Janssen's designs to increase sales through deceptive marketing are apparent on the face of its marketing plans. For example, although Janssen knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain, its Nucynta Business Plans indicated that one of the "drivers" to sell more Nucynta among primary care physicians was the "[l]ow perceived addiction and/or abuse potential" associated with the drug. However, there is no evidence that Nucynta is any less addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low. Similarly, Janssen knew that there were severe symptoms associated with opioid withdrawal including, severe anxiety, nausea, vomiting, hallucinations, and delirium, yet Janssen touted the ease with which patients could come off opioids.

i. *Janssen's Deceptive Sales Training*

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

521. For example, Janssen's sales force was trained to trivialize addiction risk. A June 2009 Nucynta training module warns that physicians are reluctant to prescribe controlled substances like

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

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

523. Similarly, a Nucynta Clinical Studies Facilitator's Guide instructs individuals training Janssen's sales representatives to ask trainees to describe a "key point"—that "83% of patients reported no withdrawal symptoms after abruptly stopping treatment without initiating alternative therapy"—"as though he/she is discussing it with a physician."

524. This misrepresentation regarding withdrawal was one of the key messages Janssen imparted to employees in the "Retail ST 101 Training" delivered to Nucynta sales representatives.

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

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

527. The misleading messages and materials Janssen provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Lorain . Janssen's nationwide messages reached County prescribers in a number of ways, including through its sales force in detailing visits, as well as through websites and ads. They were also delivered to County prescribers by Janssen's paid speakers, who were required by Janssen policy and by FDA regulations to stay true to Janssen's nationwide messaging.

ii. *Janssen's Deceptive Speakers Bureau Programs*

528. Janssen did not stop at disseminating its misleading messages regarding chronic opioid therapy through its sales force. It also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives.

529. Janssen's speakers worked from slide decks—which they were required to present—reflecting the deceptive information about the risks, benefits, and superiority of opioids outlined above. For example, a March 2011 speaker's presentation titled *A New Perspective For Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* set out the following adverse events associated with use of Nucynta: nausea, vomiting, constipation, diarrhea, dizziness, headache, anxiety, restlessness, insomnia, myalgia, and bone pain. It completely omitted the risks of misuse, abuse, addiction, hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding,

confusion, and other known, serious risks associated with chronic opioid therapy. The presentation also minimized the risks of withdrawal by stating that "more than 82% of subjects treated with tapentadol IR reported no opioid withdrawal symptoms."

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

531. These speakers presentations were part of Janssen's nationwide marketing efforts. Upon information and belief, a number of these events were available to and were intended to reach Lorain prescribers.

iii. *Janssen's Deceptive Unbranded Advertising*

532. Janssen was aware that its branded advertisements and speakers programs would face regulatory scrutiny that would not apply to its unbranded materials, so Janssen also engaged in direct, unbranded marketing.

533. One such unbranded project was Janssen's creation and maintenance of *Prescriberesponsibly.com* (last updated July 2, 2015), a website aimed at prescribers and patients that claims that concerns about opioid addiction are "overstated." A disclaimer at the bottom of the website states that the "site is published by Janssen Pharmaceuticals, Inc., which is solely responsible for its content." This website was available to and intended to reach County prescribers and patients.

b. Janssen's Deceptive Third-Party Statements

534. Janssen's efforts were not limited to directly making misrepresentations through its sales force, speakers' bureau, and website. To avoid regulatory constraints and give its efforts an appearance of independence and objectivity, Janssen obscured its involvement in certain marketing activities by "collaborat[ing] with key patient advocacy organizations" to release misleading information about opioids.

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

535. Janssen worked with AAPM and AGS to create a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009). In doing so, Janssen contracted with a medical publishing firm, Conrad & Associates, LLC. The content was drafted by a writer ("Medical Writer X") hired by Conrad & Associates and funded by Janssen. These materials were reviewed, in detail, by Janssen's medical-legal review team, which conducted detailed reviews and gave him editorial feedback on his drafts, which was adopted in the published version.

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

for chronic pain; and (c) opioids are under-prescribed because doctors are hesitant, confused, or face other barriers.[142]

537. *Finding Relief* is rife with the deceptive content. *Finding Relief* misrepresents that opioids increase function by featuring a man playing golf on the cover and listing examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The functional claims contained in *Finding Relief* are textbook examples of Defendants' use of third parties to disseminate messages the FDA would not allow them to say themselves. Compare, e.g.:

Branded Advertisement That Triggers an FDA Warning Letter (2008)[143]
Improvement in Daily Activities Includes: • Walking on a flat surface • Standing or sitting • Climbing stairs • Getting in and out of bed or bath • Ability to perform domestic duties

with:

Seemingly Independent Publication: "Finding Relief: Pain Management for Older Adults" (Final Authority, Janssen 2009):
Your recovery will be measured by how well you reach functional goals such as • Sleeping without waking from pain • Walking more, or with less pain • Climbing stairs with less pain

[142] Medical Writer X now acknowledges that the lists of adverse effects from chronic opioid use in the publications he authored, which excluded respiratory depression, overdose, and death and minimized addiction, were, "ridiculous" and "prime examples" of leaving out facts that the pharmaceutical company sponsors and KOLs knew at the time were true. His writings repeatedly described the risk of addiction as low. Medical Writer X stated that he understood that the goal was to promote opioids and, as a result, discussing addiction would be "counterproductive."

[143] This advertisement drew an FDA Warning Letter dated March 24, 2008. Though the advertisement was by drug company King, it is used here to demonstrate the types of claims that the FDA regarded as unsupported.

- Returning to work
- Enjoying recreational activities
- Having sex
- Sleeping in your own bed

538. *Finding Relief* also trivialized the risks of addiction describing as a "myth" that opioids are addictive, and asserting as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."

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

540. Finally, *Finding Relief* deceptively overstated the risks associated with alternative forms of treatment. It juxtaposed the advantages and disadvantages of NSAIDs on one page, with the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "increase[d] . . .risk of heart attack and stroke." Conversely, the only adverse effects of opioids listed by *Finding Relief* are "upset stomach or sleepiness," which the brochure claims will go away, and constipation. The guide never mentions addiction, overdose, abuse, or other serious side effects of opioids.

541. Janssen was not merely a passive sponsor of *Finding Relief*. Instead, Janssen exercised control over its content and provided substantial assistance to AGS and AAPM to distribute it. A "Copy Review Approval Form" dated October 22, 2008 indicates that key personnel from Janssen's Advertising & Promotion, Legal, Health Care Compliance, Medical Affairs, Medical Communications, and Regulatory Departments reviewed and approved *Finding Relief*. All six Janssen

personnel approving the publication checked the box on the approval form indicating that *Finding Relief* was "Approved With Changes." After the publication was modified at the behest of Janssen personnel, Janssen paid to have its sales force distribute 50,000 copies of *Finding Relief* throughout the nation. Thus, *Finding Relief* is considered labeling for Janssen's opioids within the meaning of 21 C.F.R. § 1.3(a).

542. AAPM purchased and distributed copies of *Finding Relief* to all of its members, including those who reside in Lorain .

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

ii. *AGS – Misleading Medical Education*

544. Janssen also worked with AGS on another project—AGS's CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse" although the study supporting this assertion did not analyze addiction rates by age. They also stated falsely, that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)." Based on Janssen's control over AGS's *Finding Relief*, Janssen also would have exercised control over this project as well.

iii. *APF*

545. Janssen also worked with APF to carry out its deceptive marketing campaign. Documents obtained from one of Janssen's public relations firms, Ketchum, indicate that Janssen and the firm enlisted APF as part of an effort to "draft media materials and execute [a] launch plan" for Janssen's drugs at an upcoming meeting of the AAPM. Janssen also drew on APF publications to corroborate claims in its own marketing materials and its sales training. Janssen personnel participated in a March 2011 call with APF's "Corporate Roundtable," in which they worked with APF and drug company personnel to develop strategies to promote chronic opioid therapy. APF personnel spoke with Janssen employees who "shar[ed] expertise from within their company for [a] public awareness campaign."

546. Their joint work on the "Corporate Roundtable" demonstrates the close collaboration between Janssen and APF in promoting opioids for the treatment of chronic pain. APF President Will Rowe also reached out to Defendants—including Janssen— rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine. Additional examples of APF's collaboration with Janssen are laid out below:

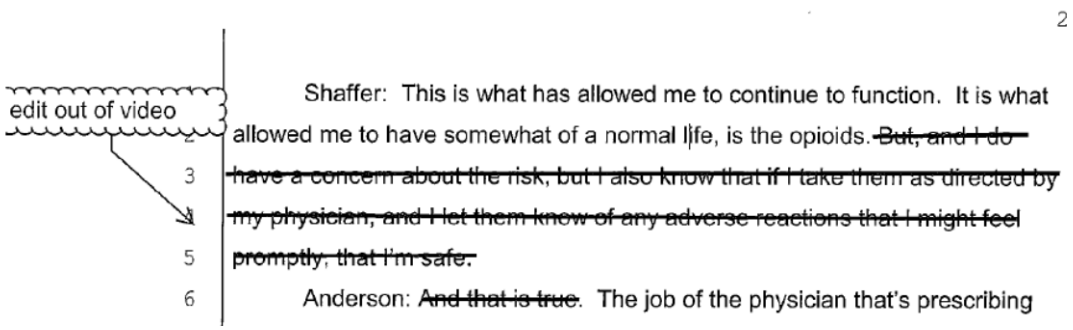
a) Let's Talk Pain

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

548. Janssen exercised substantial control over the content of the *Let's Talk Pain* website. Janssen's internal communications always referred to *Let's Talk Pain* as promoting tapentadol, the molecule it sold as Nucynta and Nucynta ER. Janssen regarded *Let's Talk Pain* and another website—*Prescriberesponsibly.com*— as integral parts of Nucynta's launch:

549. Janssen documents also reveal that Janssen personnel viewed APF and AAPM as "coalition members" in the fight to increase market share.

550. To this end, Janssen and APF entered into a partnership to "keep pain and the importance of responsible pain management top of mind" among prescribers and patients. They agreed to work to reach "target audiences" that included patients, pain management physicians, primary care physicians, and KOLs. One of the roles Janssen assumed in the process was to "[r]eview, provide counsel on, and approve materials." Janssen did in fact review and approve material for the *Let's Talk Pain* website, as evidenced by the following edits by a Janssen executive to the transcript of a video that was to appear on the site:



551. The final version of the video on *Let's Talk Pain* omitted the stricken language above.

552. This review and approval authority extended to the *Let's Talk Pain* website. Emails between Janssen personnel and a consultant indicate that, even though the *Let's Talk Pain* website was hosted by APF, Janssen had approval rights over its content. Moreover, emails describing Janssen's review and approval rights related to *Let's Talk Pain* indicate that this right extended to "major changes and video additions."

553. As a 2009 Janssen memo conceded, "[t]he *Let's Talk Pain Coalition* is sponsored by PriCara, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc." and "[t]he Coalition and Pricara **maintain editorial control of all *Let's Talk Pain* materials and publications**" (emphasis added).

554. A 2011 Consulting Agreement between Janssen and one of APF's employees, relating to the dissemination of national survey data, demonstrates the near-total control Janssen was empowered to exercise over APF in connection with the *Let's Talk Pain* website, including requiring APF to circulate and post Janssen's promotional content. The agreement required APF to "participate in status calls between Janssen, APF, AAPM, ASPMN, and Ketchum as requested by Janssen" and required APF to "respond to requests to schedule status calls **within 48 hours** of the request" (emphasis in original). APF also was required to "[r]eview and provide feedback to media materials, including a press release, pitch email, a key messages document, and social media messages, **within one week** of receipt" (emphasis in original).

555. The agreement further required APF to provide a summary of the survey results in APF's PAIN MONITOR e-newsletter, post a link to the survey results on APF's Facebook page, send out tweets related to the survey, serve as a spokesperson available for media interviews, "[s]hare information with any media contacts with whom APF has existing relationships to promote the announcement of the national survey findings," identify at least two patient spokespersons to talk about the survey data, and include the survey results in "any future APF materials, as appropriate." Tellingly, "any ideas made or conceived by [APF] in connection with or during the performance" of the Agreement "shall be the property of, and belong to, [Janssen]."

556. Janssen also exercised its control over *Let's Talk Pain*. Janssen was able to update the *Let's Talk Pain* website to describe its corporate restructuring and Janssen personnel asserted their control over "video additions" by reviewing and editing the interview touting the functional benefits of opioids. Given its editorial control over the content of *Let's Talk Pain*, Janssen was, at all times, fully aware of—and fully involved in shaping—the website's content.[144]

557. Let's Talk Pain contained a number of misrepresentations.

558. For example, *Let's Talk Pain* misrepresented that the use of opioids for the treatment of chronic pain would lead to patients regaining functionality. Let's Talk Pain featured an interview claiming that opioids were what allowed a patient to "continue to function." This video is still available today on YouTube.com and is accessible to Lorain prescribers and patients.

559. In 2009, *Let's Talk Pain* also promoted the concept of "pseudoaddiction," which it described as patient behaviors that may occur when pain is under-treated" but differs "from true addiction because such behaviors can be resolved with effective pain management" (emphasis added). *Let's Talk Pain* was available to, and was intended to, reach Lorain patients and prescribers.

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

b) Exit Wounds

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

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

c. Janssen's Deceptive Statements to Lorain Prescribers and Patients

562. Janssen also directed the misstatements described above to Lorain patients and prescribers, including through CMEs, its sales force, and recruited physician speakers.

i. *Janssen's Deceptive Medical Education Programs in Lorain*

563. Janssen sponsored CMEs and talks attended by County prescribers.

ii. *Janssen's Deceptive Detailing Practices in Lorain*

564. The experiences of specific prescribers confirm both that Janssen's national marketing campaign included the misrepresentations, and that the company disseminated these same misrepresentations to Lorain prescribers and consumers. In particular, these prescriber accounts reflect that Janssen detailers claimed that Nucynta was "not an opioid" because it worked on an "alternate receptor";[145] claimed that Janssen's drugs would be less problematic for patients because they had anti-abuse properties and were "steady state"; claimed that patients on Janssen's drugs were less susceptible to withdrawal; omitted or minimized the risk of opioid addiction; claimed or implied

[145] The FDA-approved labels for both Nucynta and Nucynta ER describe the tapentadol molecule as an "opioid agonist and a Schedule II controlled substance that can be abused in a manner similar to other opioid agonists, legal or illicit."

that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

5. Purdue

565. Purdue promoted its branded opioids—principally, Oxycontin, Butrans, and Hysingla—and opioids generally in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement. Purdue did this through its sales force, branded advertisements, promotional materials, and speakers, as well as a host of materials produced by its third-party partners, most prominently APF. Purdue's sales representatives and advertising also misleadingly implied that OxyContin provides a full 12 hours of pain relief, and its allied Front Groups and KOLs conveyed the additional deceptive messages about opioids' safety at higher doses, the safety of alternative therapies, and the effectiveness of addiction screening tools.

566. Based on the highly coordinated and uniform nature of Purdue's marketing, Purdue conveyed these deceptive messages to Lorain prescribers. The materials that Purdue generated in collaboration with third parties also were distributed or made available in Lorain . Purdue distributed these messages, or facilitated their distribution, in Lorain with the intent that Lorain prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Purdue's Deceptive Direct Marketing

567. Like the other Defendants, Purdue directly disseminated deceptive branded and unbranded marketing focused on minimizing the risks associated with the long-term use of opioids to treat chronic pain. Purdue directed these messages to prescribers and consumers through its sales force and branded advertisements.

568. Purdue engaged in in-person marketing to doctors in Lorain . Purdue had 250 sales representatives in 2007, of whom 150 were devoted to promoting sales of OxyContin full time. Like the other Defendants' detailers, Purdue sales representatives visited targeted physicians to deliver

sales messages that were developed centrally and deployed, identically, across the country. These sales representatives were critical in delivering Purdue's marketing strategies and talking points to individual prescribers.[146] Indeed, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines, which as discussed above deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories, with doctors during individual sales visits.

569. Purdue's spending on detailing reached its nadir in 2006 and 2007, as the company faced civil and criminal charges for misbranding OxyContin. Since settling those charges in 2007, however, Purdue has sharply increased its quarterly spending on promotion through its sales force, from under $5 million in 2007 to more than $30 million by the end of 2014.

570. Purdue also marketed its drugs through branded advertisements which relied on, among other deceptive tactics, misleading statements about the efficacy and onset of OxyContin. Purdue marketed its drug as effective for 12 hours while knowing that these claims were misleading because, for many patients, the pain relief lasted for as little as eight hours, leading to end-of-dose failure and withdrawal symptoms. This prompted doctors to prescribe, or patients to take, higher or more frequent doses of opioids, all of which increased the risk of abuse and addiction.

571. For example, a "Conversion and Titration Guide" submitted to the FDA and distributed to physicians by Purdue, prominently referred to "Q12h OxyContin Tablets," meaning that each tablet was intended to "offer . . . every-twelve-hour dosing." Other marketing materials directed at physicians and disseminated across the country in 2006 touted that OxyContin's "12-hour AcroContin Delivery System" was "designed to deliver oxycodone over 12 hours," which offered

[146] But Purdue did not stop there. It also tracked around 1,800 doctors whose prescribing patterns demonstrated a probability that they were writing opioid prescriptions for addicts and drug dealers. Purdue kept the program secret for nine years and, when it finally did report information about these suspicious doctors to law enforcement authorities, it only did so with respect to 8% of them.

patients "life with Q12H relief." Those same marketing materials included a timeline graphic with little white paper pill cups at "8AM" and, further down the line, at "8PM" only. They also proclaimed that OxyContin provided "Consistent Plasma Levels Over 12 Hours" and set forth charts demonstrating absorption measured on a logarithmic scale, which fraudulently made it appear that levels of oxycodone in the bloodstream slowly taper over a 12-hour time period.

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

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

574. As outlined above, however, these statements are misleading because they fail to make clear that a 12-hour dose does not equate to 12 hours of pain relief. Nevertheless, Purdue's direct marketing materials have misleadingly claimed OxyContin offers 12 hour "dosing convenience."

575. As described below, these deceptive statements regarding the efficacy of OxyContin were also carried into Lorain by Purdue's detailers.

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

577. For example, in 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted

over a span of several months. One such patient, "Paul," is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth—that there is no evidence that opioids improve patients' lives and ability to function and that there was substantial evidence to the contrary.

578. Some of the greatest weapons in Purdue's arsenal, however, were unbranded materials it directly funded and authored. These were in addition to the unbranded materials, described below, that Purdue channeled through third parties.

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

580. *Providing Relief, Preventing Abuse* also deceptively camouflaged the risk of addiction by falsely supporting the idea that drug-seeking behavior could, in fact, be a sign of "pseudoaddiction" rather than addiction itself. Specifically, it noted that the concept of "pseudoaddiction" had "emerged in the literature" to describe "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." Nowhere in *Providing Relief, Preventing Abuse* did Purdue disclose the lack of scientific evidence justifying the concept of "pseudoaddiction," or that the phrase itself had been coined by a Purdue vice president.

581. *Providing Relief, Preventing Abuse* was available nationally and was intended to reach Lorain prescribers. As described below, the deceptive statements in *Providing Relief, Preventing Abuse*

regarding addiction were the very same messages Purdue directed at Lorain prescribers through its sales force.

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

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

584. *In the Face of Pain* was available nationally and was intended to reach Lorain prescribers.

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

586. Purdue's misleading messages and materials were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and

alternatives. This deception was national in scope and included Lorain . As described above, Purdue's nationwide messages would have reached County prescribers in a number of ways. For example, they were carried into Lorain by Purdue's sales representatives during detailing visits as well as made available to Lorain patients and prescribers through websites and ads, including ads in prominent medical journals. They would have also been delivered to Lorain prescribers by Purdue's paid speakers, who were required by Purdue policy and by FDA regulations to stay true to Purdue's nationwide messaging.

b. Purdue's Deceptive Third-Party Statements

587. Purdue's efforts were not limited to making misrepresentations through its own sales force and its own branded and unbranded marketing materials. As described above, Purdue knew that regulatory constraints restricted what it could say about its drugs through direct marketing. For this reason, like the other Defendants, Purdue enlisted the help of third parties to release misleading information about opioids. The most prominent of these was APF.

i. *APF*

a) Purdue's Control of APF

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

589. Purdue exercised its dominance over APF over many projects and years. Purdue was APF's second-biggest donor, with donations totaling $1.7 million. Purdue informed APF that the grant money reflected Purdue's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," making clear that Purdue's funding depended upon APF continuing to support Purdue's business interests. Indeed, Purdue personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors

to talk about pain within companies and hospitals." Thus, Purdue suggested what role APF could play that would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups that, upon information and belief, APF reached out to. Purdue personnel remained in constant contact with their counterparts at APF.

590. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. This agreement demonstrates APF's lack of independence and its willingness to surrender to Purdue's control and commercial interests, which would have carried across all of APF's work.

591. Purdue used this agreement to conduct work with APF on the *Partners Against Pain* website. *Partners Against Pain* is a Purdue-branded site, and Purdue holds the copyright.

592. However, its ability to deploy APF on this project illustrates the degree of control Purdue exercised over APF. In 2011, it hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson; paying this consultant $7,500 in fees and expenses for 26 hours of work. Purdue would require this consultant to "to discuss and rehearse the delivery of [Purdue's] campaign messages" and Purdue

committed that "[m]essage points will be provided to [the] Consultant in advance and discussed on [a planned] call." At all times, decisions regarding the final content on the *Partners Against Pain* website were "at the sole discretion of Purdue."

593. APF also volunteered to supply one of its staff (a medical doctor or a nurse practitioner) to assist Purdue as a consultant and spokesperson for the launch of one of Purdue's opioid-related projects, *Understanding & Coping with Lower Back Pain*, which appeared on *Partners Against Pain*. One of the consultants was APF's paid employee, Mickie Brown. The consultant's services would be provided in return for a $10,000 consulting fee for APF and $1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances would be reviewed and approved by individuals working for Purdue. It was not until later that APF worried about "how Purdue sees this program fitting in with our [existing] grant request."

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

595. APF acquiesced to Purdue's frequent requests that APF provide "patient representatives" for *Partners against Pain*. Moreover, APF staff and board members and Front Groups ACPA and AAPM, among others (such as Dr. Webster), appear on *Inthefaceofpain.com* as "Voices of Hope"—"champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. APF also contracted with Purdue for a project on back pain in which, among other things, it provided a patient representative who agreed to attend a Purdue-run "media training session."

596. According to an Assurance of Voluntary Compliance ("AVC") entered into between the New York Attorney General and Purdue Pharma on August 19, 2015, *Inthefaceofpain.com* received 251,648 page views between March 2014 and March 2015. With the exception of one document

linked to the website, *Inthefaceofpain.com* makes no mention of opioid abuse or addiction. Purdue's copyright appears at the bottom of each page of the website, indicating its ownership and control of its content. There is no other indication that 11 of the individuals who provided testimonials on *Inthefaceofpain.com* received payments, according to the AVC, of $231,000 for their participation in speakers programs, advisory meetings and travel costs between 2008 and 2013. The New York Attorney General found Purdue's failure to disclose its financial connections with these individuals had the potential to mislead consumers.

597. Nowhere was Purdue's influence over APF so pronounced as it was with the APF's "Pain Care Forum" ("PCF"). PCF was and continues to be run not by APF, but by Defendant Purdue's in-house lobbyist, Burt Rosen. As described by a former drug company employee, Rosen exercised full control of PCF, telling them "what do do and how to do it." This control allowed him, in turn, to run APF as, in accordance with Rosen's thinking, "PCF was APF, which was Purdue." PCF meets regularly in-person and via teleconference, and shares information through an email listserv.

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

599. In 2007, the PCF Education Subgroup, consisting of drug companies Purdue and Alpharma, and Front Groups APF and ACPA (self-described as "industry-funded" groups),

developed a plan to address a perceived "lack of coordination" among the industry and pro-opioid professional and patient organizations. PCF members agreed to develop simplified "key" messages" to use for public education purposes. Their messages were reflected in programs like NIPC's *Let's Talk Pain* (put together by Endo and APF), and Purdue's *In the Face of Pain*.

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

601. APF showed its indebtedness to Purdue and its willingness to serve Purdue's corporate agenda when APF chairman Dr. James N. Campbell testified on the company's behalf at a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the OxyContin criminal settlement."[147] Despite its ostensible role as a patient advocacy organization, APF was willing to overlook substantial evidence—resulting in the jailing of Purdue executives—that Purdue blatantly, despite its clear knowledge to the contrary, told physicians and patients that OxyContin was "rarely" addictive and less addictive than other opioids. Like Purdue, APF ignored

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

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

602. APF President Will Rowe reached out to Defendants—including Purdue—rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine..

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

b) A Policymaker's Guide

604. Purdue provided significant funding to and was involved with APF's creation and dissemination of *A Policymaker's Guide to Understanding Pain & Its Management*, originally published in 2011 and still available online. *A Policymaker's Guide to Understanding Pain & Its Management* misrepresented that there were studies showing that the use of opioids for the long-term treatment of chronic pain could improve patients' ability to function.

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

demonstrating the safety of opioids long-term and noted that "[f]or functional outcomes, the other [studied] analgesics were significantly more effective than were opioids."[148]

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

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

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

609. Purdue provided substantial monetary assistance toward the creation and dissemination of the *Policymaker's Guide*, providing APF with $26,000 in grant money. APF ultimately disseminated *Policymaker's Guide* on behalf of Defendants, including Purdue. Purdue was not only kept abreast of

[148] Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006).

the content of the guide as it was being developed, but, based on the periodic reports APF provided to Purdue regarding its progress on the *Policymaker's Guide*, had editorial input of the contents.

610. The *Policymaker's Guide* was posted online and was available to, and intended to reach Lorain prescribers and consumers. As described below, the deceptive statements in *Policymaker's Guide* regarding addiction and functionality were the very same messages Purdue directed at Lorain through its own sales force.

c) Treatment Options: A Guide for People Living with Pain

611. Purdue's partnership with APF did not end with the *Policymaker's Guide*. Purdue also substantially assisted APF by beginning to sponsor *Treatment Options: A Guide for People Living with Pain* in 2007. Based on Purdue's control of other APF projects, Purdue also would have exercised control over *Treatment Options*.

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

613. Further, as outlined above, *Treatment Options* claims that addiction is rare and that, when it does occur, it involves unauthorized dose escalations, patients who receive opioids from multiple doctors, or theft, painting a narrow and misleading portrait of opioid addiction.

614. *Treatment Options* also promotes the use of opioids to treat long-term chronic pain by denigrating alternate treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses and inflates the number of deaths associated with NSAID use, distinguishing opioids as having less risk. According to *Treatment Options*, NSAIDs are different from opioids because opioids have "no ceiling dose." This lack of ceiling is considered to be beneficial as some patients "need" larger doses of painkillers than they are currently prescribed. *Treatment Options*

warns that the risks associated with NSAID use increased if NSAIDs are "taken for more than a period of months," but deceptively omits any similar warning about the risks associated with the long-term use of opioids.

615. *Treatment Options* was posted online and remains online today. It was available to and intended to reach Lorain prescribers and patients. As described below, the deceptive statements in *Treatment Options* regarding addiction and functionality echo the messages Purdue directed at Lorain through its own sales force. Purdue also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

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

ii. *Purdue's Work with Other Third Party Front Groups and KOLs*

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

a) FSMB – Responsible Opioid Prescribing

618. In 2007, Purdue sponsored FSMB's *Responsible Opioid Prescribing*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* also was drafted by Dr. Scott Fishman.

619. Purdue spent $150,000 to help FSMB distribute *Responsible Opioid Prescribing*. The book was distributed nationally, and was available to and intended to reach prescribers in Lorain .

b) AGS – Pharmacological Management of Persistent Pain in Older Persons

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

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

622. AGS sought and obtained grants from Endo and Purdue to distribute *Pharmacological Management of Persistent Pain in Older Persons*. As a result, the publication was distributed nationally, and was available to and was intended to reach Lorain prescribers. Indeed, internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Purdue

discussed treatment guidelines that minimized the risk of addiction to opioids with doctors during individual sales visits.[149]

c) *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*

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

d) *Managing Patient's Opioid Use: Balancing the Need and Risk*

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

e) *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*

625. Purdue also sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. *Path of the Patient* was devoted entirely to the message of treating

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

chronic pain with opioids. Although the program purported to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it does no such thing.

626. This "educational" program, addressing treatment of a population known to be particularly susceptible to opioid addiction, presents none of the alternative treatment options available, only discussing treatment of chronic pain with opioids.

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

f) *Overview of Management Options*

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

iii. *Purdue's Misleading Science*

629. Purdue also misrepresented the risks associated with long-term opioid use by promoting scientific studies in a deceptive way. In 1998, Purdue funded two articles by Dr. Lawrence Robbins, which showed that between 8% and 13% of the patients he studied became addicted to opioids—a troubling statistic for Purdue, whose market, and marketing, depended upon the claim that opioids were rarely addictive.[150] Purdue had these articles placed in headache-specific journals where they would be less likely to be encountered by pain specialists or general practitioners. The first of these articles has been cited a mere 16 times; the second does not even appear on Google scholar. Five years later, Purdue funded a study of OxyContin in diabetic neuropathy patients, which was published in 2003. Notwithstanding the fact that that Purdue-funded studies, testing Purdue's own drugs, had previously indicated that addiction rates were between 8% and 13%, Purdue's 2003 article reached back to the 1980 Porter-Jick Letter to support its claim that OxyContin was not commonly addictive. This article was placed in a prominent pain journal and has been cited 487 times.[151] While this article was drafted over a decade ago, it continues to be relied upon to further the misrepresentations that opioids are not addictive.

a) Purdue's Deceptive Statements to Lorain Prescribers and Patients

630. Purdue directed the dissemination of the misstatements described above to Lorain patients and prescribers through the Front Groups, KOLs, and publications described above, as well as through its sales force in Lorain and through advertisements in prominent medical journals. The deceptive statements distributed through each of these channels reflect a common theme of

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

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

misrepresenting the benefits of Purdue's opioids, unfairly portraying the risks of addiction associated with their use, and deceptively implying that they would improve patients' ability to function.

631. The deceptive message that OxyContin provided 12 hours of pain relief was not only available to, and intended to, reach Lorain prescribers through nationally circulated advertising, but was also carried directly into the offices of Lorain doctors by Purdue's sales representatives.

632. Likewise, the deceptive messages minimizing addiction were not only directed at Lorain patients and prescribers through the publications circulated above, but were also disseminated directly by Purdue's sales force.

633. Purdue also used its sales force to disseminate misleading statements about the ability of opioids to improve functionality.

634. Purdue's national marketing campaign included the misrepresentations described above and the company disseminated these same misrepresentations to Lorain prescribers and consumers. In particular, these prescriber accounts reflect that Purdue detailers omitted or minimized the risk of opioid addiction; claimed that Purdue's drugs would be less problematic for patients because they had extended release mechanisms, were tamper proof, and were "steady state"; claimed that OxyContin would provide 12 hours of pain relief; represented that screening tools could help manage the risk of addiction; minimized the symptoms of withdrawal; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

635. A survey of a sample of physicians, who reported the messages that they retained from detailing visits and other promotional activity, documented that Purdue sales representatives from at least between 2008 and 2012, promoted OxyContin as being effective for a full 12 hours. Purdue sales representatives also promoted OxyContin as improving patients' sleep (an unsubstantiated functional improvement) to an orthopedic surgeon in 2006 and to a physicians' assistant in 2013.

Purdue sales representatives also told internists that the reformulation of OxyContin prevented illegal drug use and that the formulation was 'less addicting," rather than being harder to adulterate. In 2011 Purdue sales representatives also claimed that the sustained-release property of OxyContin reduced patient "buzz," which is neither based on scientific evidence nor true.

636. The same survey indicated that Purdue sales representatives promoted its Schedule III opioid Butrans as having low or little abuse potential.

6. Insys

637. Insys was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur "known for applying aggressive marketing tactics and sharp price increases on older drugs."[152]

638. In 2012, Insys received U.S. Food and Drug Administration approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain. However, Insys encountered significant obstacles due to insurers employing a process known as prior authorization. Prior authorization prevents the over prescription and abuse of powerful and expensive drugs. The prior authorization process requires "additional approval from an insurer or its pharmacy benefit manager before dispensing…" and may also impose step therapy which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach. [153]

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[152] U.S. senate Homeland Security & Governmental Affairs Committee, *Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (quoting *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall Street Journal (Nov. 22, 2016) (www.wsj.com/articles/fentanylbillionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968)).

[153] Senate Permanent Subcommittee on Investigations, *Combatting the Opioid Epidemic: A Review of Anti-Abuse Efforts in Medicare and Private Health Insurance Systems*; see also Department of Health and Human Services, Centers for Medicare & Medicaid Services, *How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage Use Pharmacies, Formularies, & Common Coverage Rules*

639. Insys circumvented this process by forming a prior authorization unit, known at one point as the Insys Reimbursement Center ("IRC"), to facilitate the process using aggressive and likely illegal marketing techniques. Insys published education articles that praised their products' non-addictive nature; and funded patient advocacy groups who unknowingly promoted Insys' agenda of raising the profile of pain so that drugs could be prescribed to treat it. Furthermore, Insys' former sales representatives, motivated by corporate greed, paid off medical practitioners to prescribe Subsys in spite of any medical need.[154] Insys employees were pressured internally and received significant monetary incentives to increase the rate of prescription approvals.[155]

640. According to a federal indictment and ongoing congressional investigation by Sen. Claire McCaskill, IRC employees pretended to be with doctors' offices and falsified medical histories of patients. The report, acquired by McCaskill's investigators, includes transcripts and an audio recording of employees implementing these techniques in order to obtain authorization from insurers and pharmacy benefit managers. The transcript reveals an Insys employee pretending to call on behalf of a doctor and inaccurately describes the patient's medical history.[156] For example, Insys employees would create the impression that the patient had cancer, without explicitly saying so, because cancer was a requirement for prior clearance to prescribe Subsys. Insys was warned by a consultant that it lacked needed policies for governing such activities, but the executives failed to implement corrective internal procedures.

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[154] Lopez, Linette. "It's been a brutal week for the most shameless company in the opioid crisis- and it's about to get worse," *Business Insider,* http://www.businessinsider.com/opioid-addiction-drugmaker-insys-arrests-justice-department-action-2017-7

[155] Boyd, Roddy. *Murder Incorporated: Insys Therapeutics. Part 1.* Southern Investigative Reporting Foundation. http://sirf-online.org/2015/12/03/murder-incorporated-the-insys-therapeutics-story/; see also Indictment. *United States v. Babich, et al.*, D. Mass. (No. 1;16 CR 10343).

[156] U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic: Insys Therapeutics and the Systematic Manipulation of Prior Authorization, see p. 7-10.*

641. In a class action law suit against Insys, it was revealed that management "was ware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients," and an Oregon Department of Justice Investigation found that 78% of preauthorization forms submitted by Insys on behalf of Oregon patients were for off-label uses. [157] Physicians are allowed to prescribe medications for indications outside of FDA guidelines if they see fit, but it is illegal for pharmaceutical companies to market a drug for off-label use.

642. In 2008, biopharmaceutical company Cephalon settled with the U.S. Government for 425 million in a suit against the company that alleged it marketed drugs for unapproved uses (off-label). The FDA approved the drug only for opioid tolerant cancer patients. According to the Oregon settlement and class-action lawsuit, at least three employees involved in sales and/or marketing at Cephalon had moved over to Insys Therapeutics.[158]

643. Additionally, Insys created a "legal speaker program" which turned out to be a scam. The Justice Department commented on the program and stated:

> The Speaker Programs, which were typically held at high-end restaurants, were ostensibly designed to gather licensed healthcare professionals who had the capaCounty to prescribe Subsys and educate them about the drug. In truth, the events were usually just a gathering of friends and co-workers, most of whom did not have the ability to prescribe Subsys, and no educational component took place. "Speakers" were paid a fee that ranged from $1,000 to several thousand dollars for attending these dinners. At times, the sign-in sheets for the Speaker Programs were forged so as to make it appear that the programs had an appropriate audience of healthcare professionals.

644. Insys paid hundreds of thousands of dollars to doctors in exchange for prescribing Subsys and three top prescribers have already been convicted of taking bribes.

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[157] Gusovsky, Dina. The Pain Killer: *A drug Company Putting Profits Above Patients,* CNBC (https://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html)

[158] *Id.*

645. Fentanyl products are considered to be the most potent and dangerous opioids on the market and up to 50 times more powerful than heroine.[159]

646. In an internal presentation dated 2012 and entitles, "2013 SUBSYS Brand Plan," Insys identified one of six "key strategic imperatives" as "Mitigate Prior Authorization barriers."[160] On a later slide, the company identified several tasks associated with this effort, including "Build internal [prior authorization] assistance infrastructure," "Establish an internal 1-800 reimbursement assistance hotline," and "Educate field force on [prior authorization] process and facilitation."[161]

647. Additional materials produced by Insys to the minority staff suggest, however, that Insys did not match these efforts with sufficient compliance processes to prevent fraud and was internally aware of the danger of problematic practices. Specifically, on February 18, 2014, Compliance Implementation Services (CIS)—a healthcare consultant—issued a draft report to Insys titled, "Insys Call Note, Email, & IRC Verbatim Data Audit Report."[162] The introduction to the report explained that "CIS was approached by INSYS' legal representative … on behalf of the Board of Directors for Insys to request that CIS support in review of certain communications with Health Care Professionals (HCPs) and INSYS employees, and report how there were being documented."[163] Insys had expressed concerns "with respect to communications with HCPs by INSYS employees being professional in

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[159] U.S. Department of Justice. Drug Enforcement Administration. *A Real Threat to Law Enforcement: Fentanyl.* https://www.dea.gov/druginfo/DEA%20Targets%20Fentanyl%20%20A%20Real%20Threat%20to%20Law%20Enforcement%20(2016).pdf

[160] U.S. senate Homeland Security & Governmental Affairs Committee, *Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (quoting Insys Therapeutics, Inc., *2013 Subsys Brand Plan, 2012 Assessment* (2012) (INSYS_HSGAC_00007472)).

[161] *Id.* at INSYS_HSGAC_00007765.

[162] U.S. senate Homeland Security & Governmental Affairs Committee, *Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (quoting Compliance Implementation Services, Insys Call Note, Email & IRC Verbatim Data Audit Report (Feb. 18, 2014) (INSYS_HSGAC_00007763)).

[163] *Id.* at INSYS_HSGAC_00007765.

nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements."[164] An additional concern "stemmed from the lack of monitoring of commercial activities where these types of interactions could occur."[165]

648. Given these issues, Insys requested that CIS review—in part—"the general communications from the INSYS Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers … to ensure they were appropriate in nature with respect to specific uses of SUBSYS, INSYS' commercially marketed product."[166]

649. According to the findings CIS issued, Insys lacked formal policies governing the actions of its prior authorization unit. For example, "[n]o formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, [health care insurers (HCIs)], or patients exists…that governs the support function of obtaining a prior authorization for the use of SUBSYS."[167]

650. In addition, the report noted that "there were also gaps in formally approved foundational policies, procedures, and [standard operating procedures] with respect to required processes specifically within the IRC."[168]

651. In fact, "[t]he majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast."[169]

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[164] *Id.*

[165] *Id.*

[166] *Id.*

[167] *Id.* at INSYS_HSGAC_00007770.

[168] *Id.* at INSYS_HSGAC_00007768.

[169] *Id.* at INSYS_HSGAC_00007771.

652. Although four informal standard operating procedures existed with regarded to IRC functions, these documents "lacked a formal review and approval" and failed to "outline appropriately the actions performed within the IRC."[170]

653. The report also explains that Insys lacked procedures for auditing interactions between IRC employees and outside entities. According to CIS, "no formal, documented, or detailed processes by which IRC representatives' calls via telephone were audited for proper communication with HCPs or HCIs in any fashion [existed] other than random physical review of a call in a very informal and sporadic manner."[171]

654. More broadly, the report notes that "no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients."[172]

655. At the end of the report, CIS provided a number of recommendations concerning IRC activities. First, CIS suggested that IRC management "formally draft and obtain proper review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs."[173]

656. Similarly, IRC management was urged to formally draft IRC-specific standard operating procedures "specific to each job function within the IRC," accompanied by "adequate training and understanding of these processes."[174] To ensure compliance with IRC standards, Insys was also directed to create an electronic system to allow management "to monitor both live and

[170] *Id.* at INSYS_HSGAC_00007770.

[171] *Id.* at INSYS_HSGAC_00007769.

[172] *Id.* at INSYS_HSGAC_00007771.

[173] *Id.* at INSYS_HSGAC_00007770.

[174] *Id.* at INSYS_HSGAC_00007771.

anonymously IRC employee communications both incoming and outgoing."[175] Finally, CIS recommended that Insys institute a formal process for revising and updating "IRC documentation used for patient and HCP data."[176]

657. The CIS report concluded by noting, in part, that a review of ten conversations between IRC employees and healthcare providers, office staff, and insurance carriers revealed "that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of SUBSYS communicated."[177]

658. Yet within a year of this conclusion, according to the recording transcribed below, an Insys IRC employee appears to have misled a PBM representative regarding the IRC employee's affiliation and the diagnosis applicable to Sarah Fuller. The alleged result, in that case, was death due to inappropriate and excessive Subsys prescriptions.

659. One former Insys sales representative described the motto of this approach to patients as "Start them high and hope they don't die."[178]

E. The Result of Defendants' Fraudulent Scheme

660. Through their direct promotional efforts, along with those of the third-party Front Groups and KOLs they assisted and controlled, and whose seemingly objective materials they distributed, Defendants accomplished exactly what they set out to do: change the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain. As a result, Lorain doctors began prescribing opioids long-term to treat chronic pain—something most would never have considered prior to Defendants' campaign.

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[175] *Id.*

[176] *Id.*

[177] *Id.* at INSYS_HSGAC_00007772.

[178] Amended Class Action Complaint, *Larson v. Insys Therapeutics Inc.* (D. Ariz. Oct. 27, 2014.)

661. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

1. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Lorain .

662. In the first instance, the County was damaged directly, through its payments of false claims for chronic opioid therapy by (a) partially funding a medical insurance plan for its employees and (b) its workers' compensation program.

663. Defendants' marketing of opioids caused health care providers to prescribe, and the County, through partially funding a medical insurance plan for its employees and its workers' compensation program, to pay for prescriptions of opioids to treat chronic pain. Because of Defendants' unbranded marketing, health care providers wrote and the County paid for prescriptions of opioids for chronic pain that were filled not only with their drugs, but with opioids sold by other manufacturers. All of these prescriptions were caused by Defendants' fraudulent marketing and therefore all of them constitute false claims. Because, as laid out below, the County is obligated to cover medically necessary and reasonably required care, it had no choice but to pay for these false and fraudulent claims.

664. The fact that the County would pay for these ineligible prescriptions was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, and government payors such as Lorain , to pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

a. Increase in Opioid Prescribing Nationally

665. Defendants' scheme to change the medical consensus regarding opioid therapy for chronic pain was greatly successful. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide, rising to 257 million in 2009.[179]

666. Opioid prescriptions increased even as the percentage of patients visiting doctors for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline of NSAID use.[180]

667. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids. Indeed, "[o]pioids are the most common means of treatment for chronic pain."[181] From 1980 to 2000, opioid prescriptions for chronic pain visits doubled. This resulted not from an epidemic of pain, but an epidemic of prescribing. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010—even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications ***decreased***. For back pain alone—one of the most common chronic pain conditions—the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady—and climbing.

668. This increase corresponds with, and was caused by, Defendants' massive marketing push. As reflected in the chart below, according to data obtained from a marketing research company, Defendants' spending on marketing of opioids nationwide—including all of the drugs at

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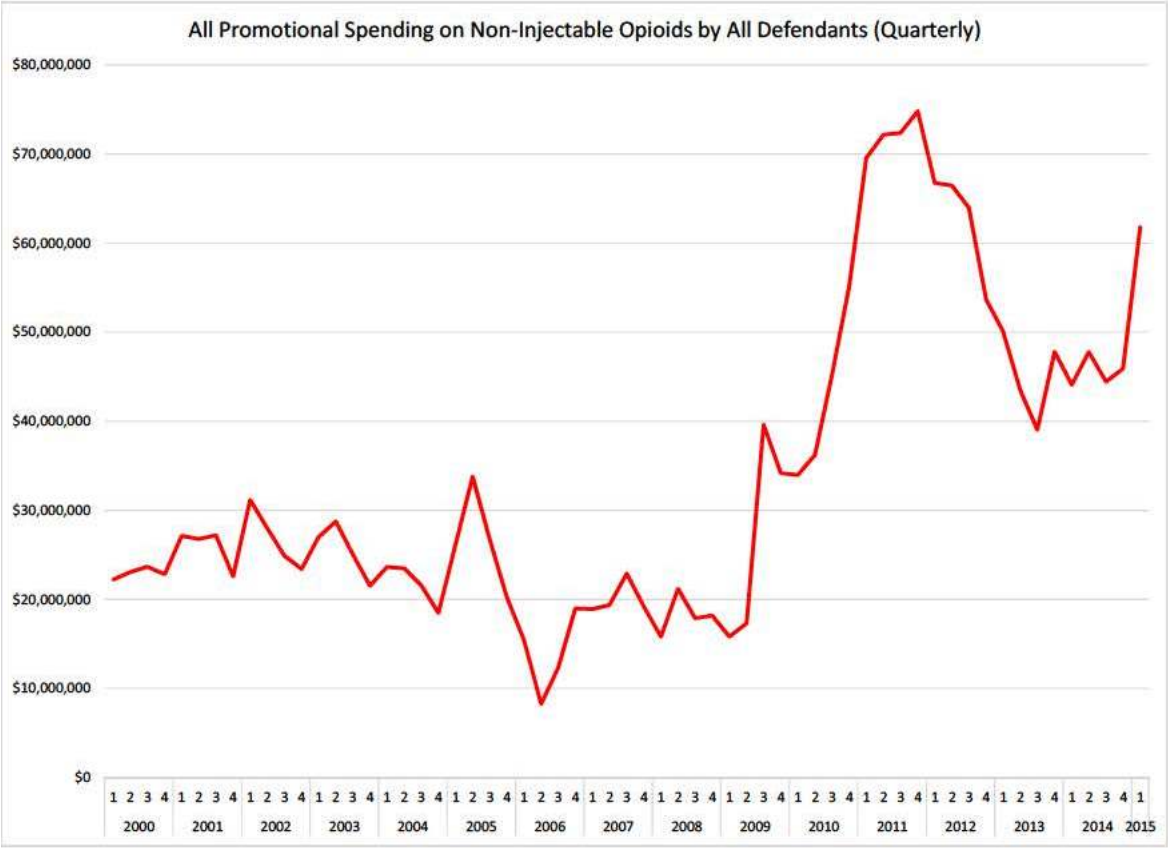
[179] Office of National Drug Control Policy, *2011 Prescription Drug Abuse Prevention Plan,* Whitehouse.gov, (no longer available on whitehouse.gov), https://obamawhitehouse.archives.gov/ondcp/prescription-drug-abuse1

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

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

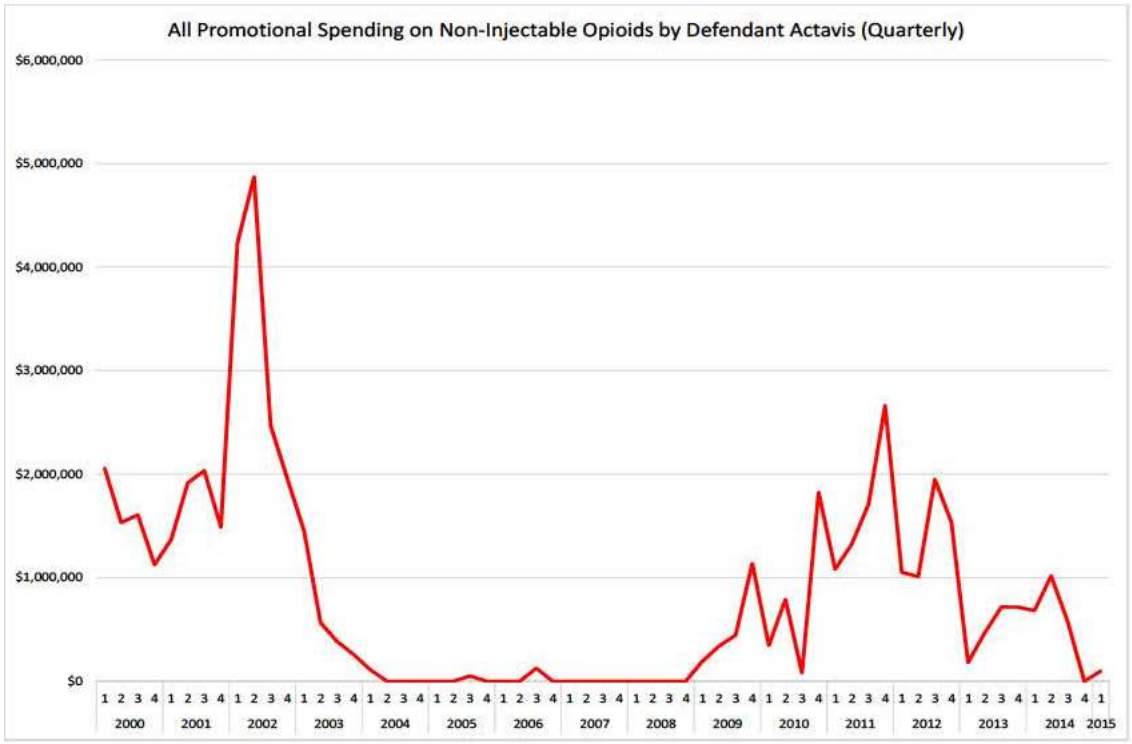
issue here—stood at more than $20 million per quarter and $91 million annually in 2000. By 2011, that figure hit its peak of more than $70 million per quarter and $288 million annually, an increase of more than three-fold. By 2014, the figures dropped to roughly $45 million per quarter and $182 million annually, as Defendants confronted increasing concerns regarding opioid addiction, abuse, and diversion, and as Janssen, which accounted for most of the spending reduction, prepared to sell its U.S. rights to Nucynta and Nucynta ER. Even so, Defendants still spent double what they had spent in 2000 on opioid marketing.



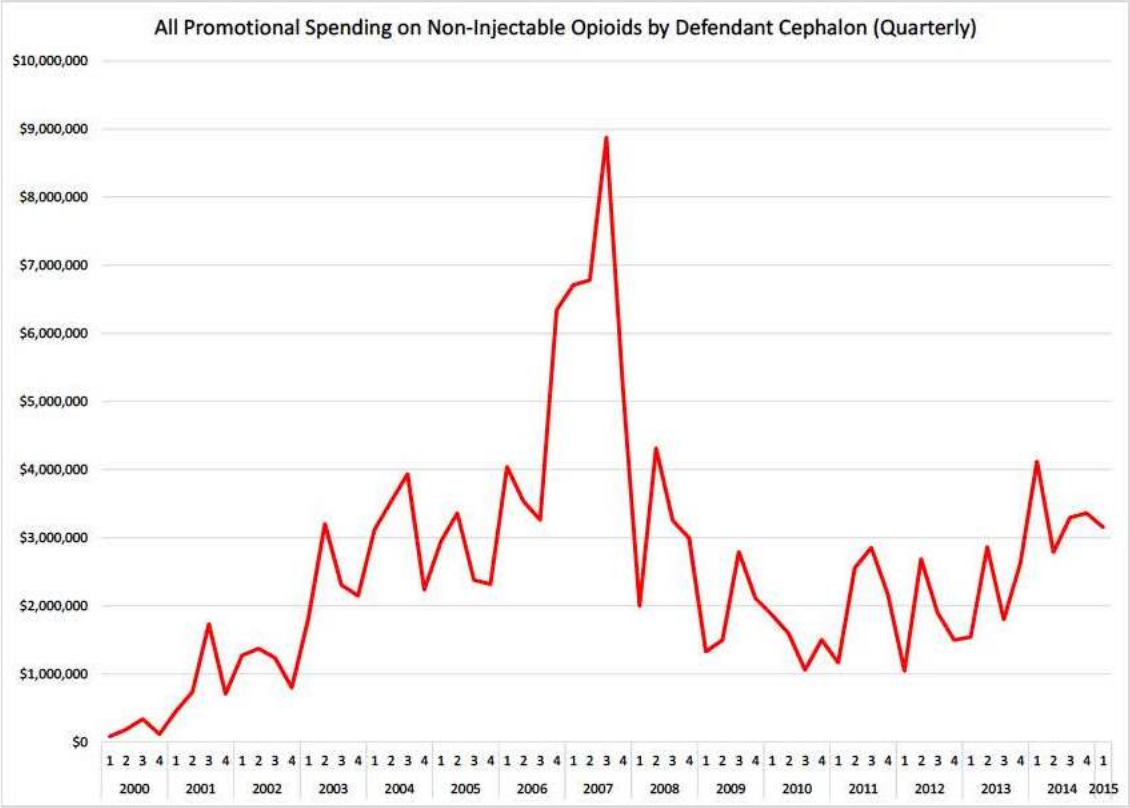
669. Defendants' opioid detailing visits to individual doctors made up the largest component of this spending, with total detailing expenditures more than doubling between 2000 and 2014 to $168 million annually.

670. Each Defendant's promotional spending reflects its participation in this marketing blitz. Between 2000 and 2011:

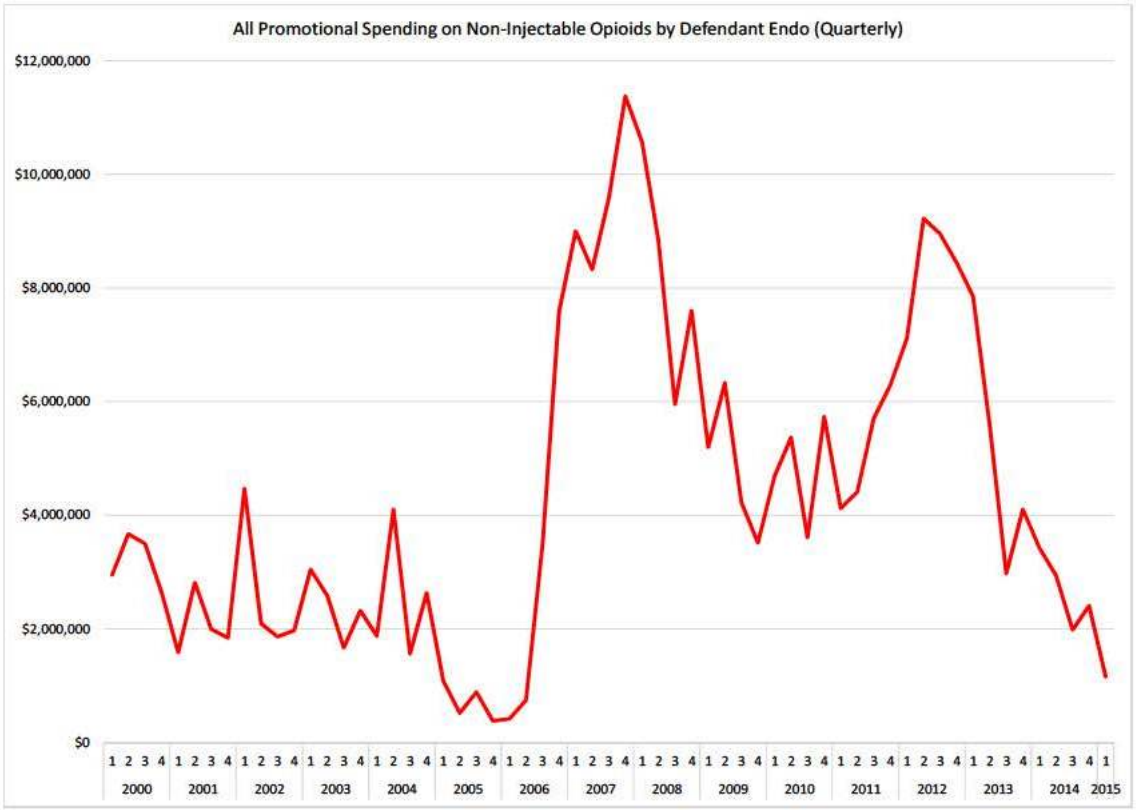
- Actavis's promotional spending, which was virtually nonexistent in the 2004-2008 period, began to sharply rise 2009. The third quarter of 2011 saw a peak of $3 million at one point in 2011 and nearly $7 million for the year, as shown below:



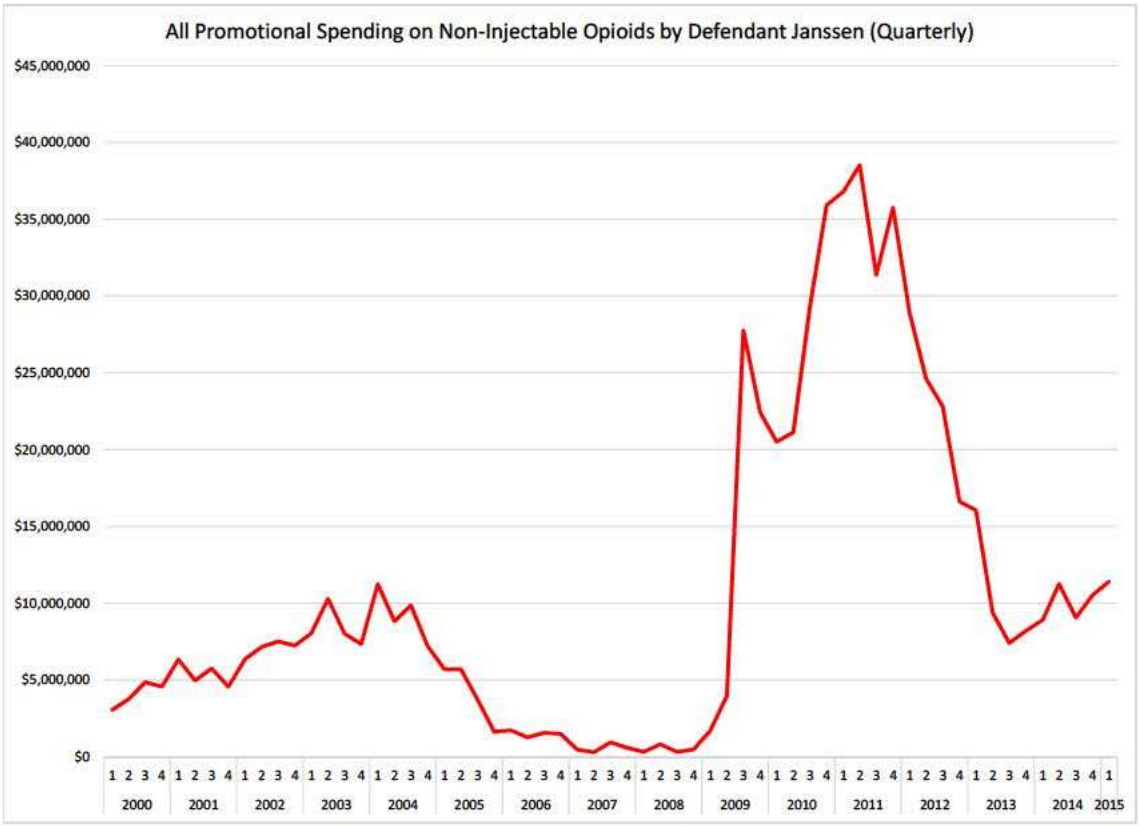
- Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $4 million in 2014 (and more than $13 million for the year), including a peak, coinciding with the launch of Fentora, of nearly $9 million half way through 2007 (and more than $27 million for the year), as shown below:



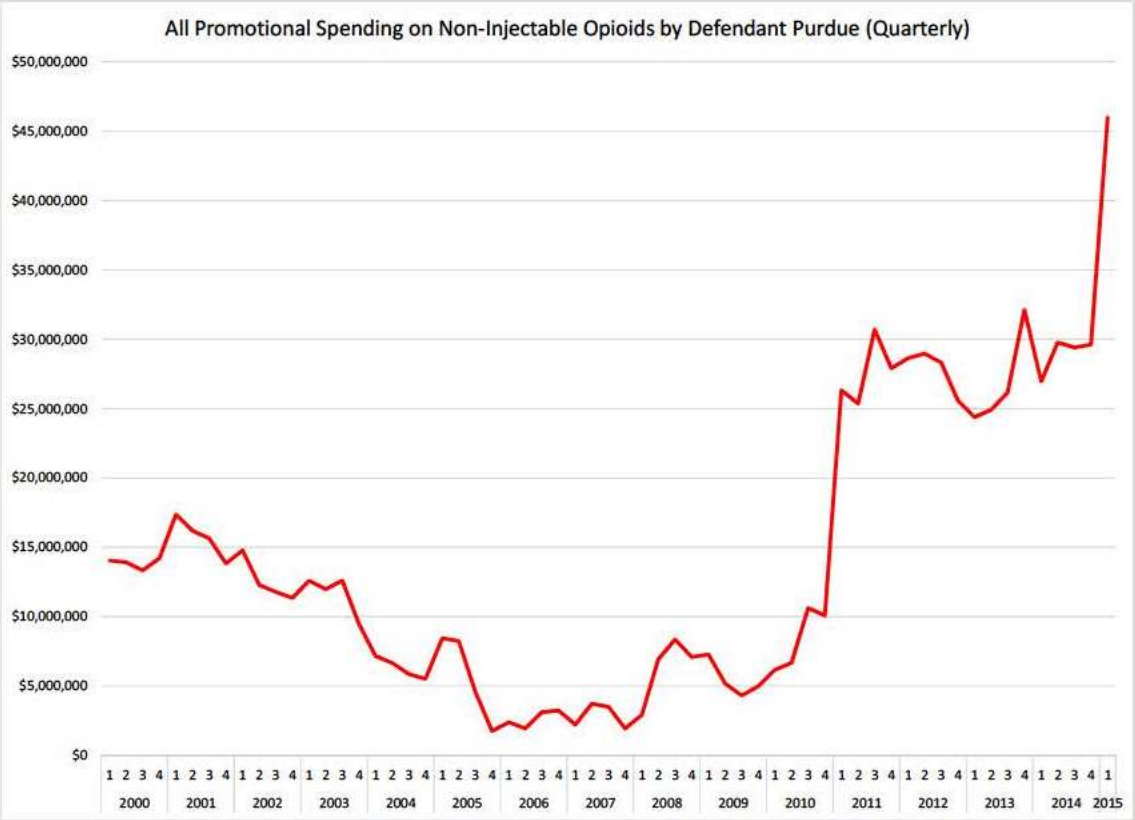
- Endo 's quarterly spending went from the $2 million to $4 million range from 2000 to 2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



- Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011) as shown below:



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



a. The County's Increased Spending on Opioids

671. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend millions of dollars each year in its efforts to combat the public nuisance

created by Defendants' deceptive marketing campaign. Plaintiff has incurred, and continues to incur, costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents.

i. *Defendants' Misrepresentations Were Material*

672. Defendants' misrepresentations were material to, and influenced, the County's decisions to pay claims for opioids for chronic pain (and, therefore, to bear its consequential costs in treating overdose, addiction, and other side effects of opioid use). In the first instance, the County would not have been presented with, or paid, claims for opioids that would not have been written but for Defendants' fraudulent and deceptive marketing. Second, the County has demonstrated that Defendants' marketing is material by taking further steps to ensure that the opioids are only prescribed and covered when medically necessary or reasonably required.

673. As laid out above, Defendants' misrepresentations related to the County's requirement that medical treatments be medically necessary or reasonably required – a condition of payment for any medical treatment under the County's health plans and workers' compensation program. But for Defendants' fraudulent and deceptive marketing, prescribers would have accurately understood the risks and benefits of opioids and would not have prescribed opioids where not medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but the core of prescribers' decision-making.

674. It is the County's practice not to pay claims that are not medically necessary or reasonably required. However, the County would not have known whether a prescriber had made an

informed judgment that a particular claim for opioids was medically necessary or reasonably required, or, conversely had acted under the influence of Defendants' fraudulent and deceptive marketing. It is not clear from the face of a claim whether: (1) the patient suffered from cancer or another terminal condition, for example, where long-term prescribing was medically necessary or appropriate; or (2) the prescriber was exposed to Defendants' marketing materials, treatment guidelines, or education programs, or visited by a drug representative who engaged in affirmative misrepresentations or omissions, for example.

ii. *The County's Increased Costs Correlate with Defendants' Promotion*

675. The County's spending on opioids rose along with Defendants' spending to promote opioids. That spending had a direct impact on opioid use (and its consequences in abuse, addiction, and overdose) in Lorain .

676. It is also distressing (and a sign of further problems ahead) that the drop in opioid prescribing beginning in 2014 has been accompanied by a corresponding increase in Defendants' promotional spending, which is headed towards a new high, despite evidence of the grave toll that opioids are taking on law enforcement, public health, and individual lives.

2. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Lorain Consumers.

a. Increased Opioid Use Has Led to an Increase in Opioid Abuse, Addiction, and Death

677. Nationally, the sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and opioid abuse. "Deaths from opioid overdose have risen steadily since 1990 in parallel with

increasing prescription of these drugs."[182] Prescription opioid use contributed to 16,917 overdose deaths nationally in 2011—more than twice as many deaths as heroin and cocaine combined; drug poisonings now exceed motor vehicle accidents as a cause of death. More Americans have died from opioid overdoses than from participation in the Vietnam War.

678. Contrary to Defendants' misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet. According to the CDC, the 80% of opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or "doctor-shoppers") account for 20% of all prescription drug overdoses.

679. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).

680. Emergency room visits tied to opioid use likewise have sharply increased in Lorain .

681. Widespread opioid use and abuse in Lorain are problems even when they do not result in injury or death. Opioid addiction is affecting residents of all ages, ethnicities, and socio-economic backgrounds in the County. Many addicts start with a legal opioid prescription—chronic back pain, fibromyalgia, or even dental pain—and do not realize they are addicted until they cannot stop taking the drugs.

682. These glaring omissions, described consistently by counselors and patients, mirror and confirm Defendants' drug representatives' own widespread practice, as described above, of omitting

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

any discussion of addiction from their sales presentations to physicians or in their "educational" materials.

b. Increased Opioid Use Has Increased Costs Related to Addiction Treatment

683. Lorain has opioid treatment programs, Substance Alternative Clinics, that provide a comprehensive treatment program for persons addicted to heroin or other opioids.

684. In addition to intense counseling, many treatment programs prescribe additional drugs to treat opioid addiction. Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction—buprenorphine/naloxone and naltrexone—were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payors to be $72.5 billion.

c. Increased Opioid Use Has Fueled An Illegal Secondary Market for Narcotics and the Criminals Who Support It

685. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme supplies both ends of the secondary market for opioids—producing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that a "substantial increase in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of prescriptive use."[183] It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

686. A significant black market in prescription opioids also has arisen, not only creating and supplying additional addicts, but fueling other criminal activities.

[183] G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) JAMA 1865 (2012).

687. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals. In 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006. Nearly 80% of those who used heroin in the past year had previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street. In the words of one federal DEA official, "Who would have ever thought in this country it would be cheaper to buy heroin than pills . . . [t]hat is the reality we're facing."[184]

688. That reality holds true in Lorain . According to addiction programs in the County, a typical course sees addicts requesting more and more opioids from their doctors, who eventually cut them off. Many addicts then doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the breaking point, or after turning to criminal activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean; repeated relapse is common.

3. Defendants' Fraudulent Marketing Has Led to Record Profits

689. While the use of opioids has taken an enormous toll on Lorain and its residents, Defendants have gained blockbuster profits. In 2012, health care providers wrote 259 million

[184] Matt Pearce & Tina Susman, *Philip Seymour Hoffman's death calls attention to rise in heroin use*, L.A. Times, Feb. 3, 2014, http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204.

prescriptions for opioid painkillers[185]—roughly one prescription per American adult. Opioids generated $8 billion in revenue for drug companies just in 2010.

690. Financial information—where available—indicates that Defendants each experienced a material increase in sales, revenue, and profits from the fraudulent, misleading, and unfair market activities laid out above. Purdue's OxyContin sales alone increased from $45 million in 1996 to $3.1 billion in 2010. In 2010, Research Firm Frost & Sullivan projected an increase to $15.3 billion in overall revenue from opioid sales by 2016.

4. Defendants Fraudulently Concealed Their Misrepresentations

691. At all times relevant to this Complaint, Defendants took steps to avoid detection of, and fraudulently conceal, their deceptive marketing and conspiratorial behavior.

692. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

693. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and exerting final approval over their content. Defendants exerted their considerable influence on these promotional and "educational" materials.

694. 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 as if they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning

[185] Press Release,Center for Disease Control, Opioid painkiller prescribing varies widely among states: Where you live makes a difference (July 1, 2014), https://www.cdc.gov/media/releases/2014/p0701-opioid-painkiller.html

or import of studies they cited and offered them as evidence for propositions they did not actually 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, nor could they have been detected by the County.

695. Thus, while the opioid epidemic was evident, Defendants, in furtherance of their respective marketing strategies, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that the County now asserts. The County was not alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

696. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the County of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

G. Through Their Public Statements, Marketing, And Advertising, Defendants' Deceptions Deprived Plaintiff Of Actual Or Presumptive Knowledge Of Facts Sufficient To Put Them On Notice Of Potential Claims. Defendants Entered Into And Engaged In A Civil Conspiracy.

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

698. Defendants reached an agreement between themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, and others through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

699. This network is interconnected and interrelated and relied upon Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs,

patient education materials, and Front Groups. These materials were developed and funded collectively by Defendants, and Defendants relied upon the materials to intentionally mislead consumers and medical providers of the appropriate uses, risks and safety of opioids.

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

701. The Distributor Defendants are opioid distributors in Lorain County.

702. The Distributor Defendants purchased opioids from manufacturers, such as the named defendants herein, and sold them to pharmacies throughout Lorain County.

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

704. Pursuant to Section 4729-9 of the Ohio Administrative Code, entitled "Dangerous Drugs", distributors/wholesalers such as the defendants are required to create record keeping, including establishing and maintaining inventories and records of all transactions of dangerous drugs such as opioid pain medications. Pursuant to section (i) "[T]he wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

705. According to the Drug Enforcement Administration Automation of Reports and Consolidated Orders System ("ARCOS"), from 2006 to 2016 pharmaceutical distributors, including Defendants, a drastically increasing number of opioid pain medications to the Lorain area.

706. From 2006 through 2016, pharmaceutical distributors distributed over 1.1 million grams of opioids pain pharmaceuticals to Lorain County at the retail level.

707. The number of grams distributed to Lorain County rose at an alarming rate. For example, in 2006, approximately 82,000 grams of opioids were distributed at the retail level. By 2011,

this number rose to over 120,000. Even as recently as 2014 there were over 100,000 grams of opioids distributed to Lorain County.

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

709. The Defendants were each on notice that there was an alarming and suspicious rise in manufacturing and distributing opioids to retailers within Lorain County during this time period.

710. As entities involved in the manufacture and distribution of opioid medications, Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under Ohio law.

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

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

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

714. The Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the manufacture and flow of these drugs to Lorain County.

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

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

717. In 2008, McKesson paid a $13.25 million fine to settle similar claims regarding suspicious orders from internet pharmacies.[186]

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

719. According to the DEA, McKesson "supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills" during the time in question, and "frequently misused products that are part of the current opioid epidemic."[187]

720. On January 17, 2017, the DEA announced that McKesson had agreed to pay a record $150 million fine and suspend the sale of controlled substances from distribution centers in several states.[188]

721. In 2008, defendant Cardinal paid a $34 million penalty to resolve allegations that it failed to report suspicious opioid orders.[189]

722. Despite this past penalty, in 2017, it was announced that defendant Cardinal agreed to a $44 million fine to "resolve allegations that it failed to alert the Drug Enforcement Agency to suspicious orders of powerful narcotics by pharmacies in Florida, Maryland, and New York.[190]

723. Defendant AmeriSource faced a criminal inquiry "into its oversight of painkiller sales" in 2012.191 They have paid out fines for similar claims to the state of West Virginia.

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[186] http://www.wvgazettemail.com/news-health/20161218/suspicious-drug-order-rules-never-enforced-by-state (accessed May 30, 2017).
[187] https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (accessed May 30, 2017).
[188] *Id.*
[189] https://www.justice.gov/usao-wdwa/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under-0 (access May 30, 2017).
[190] https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.7049c4431465 (accessed on May 30, 2017).
[191] http://www.nytimes.com/2013/06/12/business/walgreen-to-pay-80-million-settlement-over-painkiller-sales.html (accessed on May 30, 2017).

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

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

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

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

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

729. The Defendants manufactured and delivered an excessive and unreasonable amount of opioid pain medications to retailers in Lorain County.

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

731. The Defendants knew or should have known that they were manufacturing and distributing levels of opioid medications that far exceeded the legitimate needs of Lorain County.

732. The Defendants also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications within Lorain County.

733. The Defendants made substantial profits from the opioids sold in Lorain County.

734. The Defendants violated the Ohio law and regulations for manufacturers and distributors, by failing to properly report suspicious orders.

735. By the actions and inactions described above, the Defendants showed a reckless disregard for the safety of the residents of Lorain County.

736. By the actions and inactions described above, the Defendants caused great harm to Lorain County.

737. On December 27, 2007, the U.S. Department of Justice, Drug Enforcement Administration, sent a letter to Cardinal stating, "This letter is being sent to every entity in the United States registered with the Drug Enforcement Agency (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b)."

738. The DEA has provided briefings to each of the Defendant Distributors and conducted a variety of conferences regarding their duties under federal law.

739. The DEA sent a letter to each of the Defendant Distributors on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

740. The DEA sent a second letter to each of the Defendant Distributors on December 27, 2007. This letter reminded the Defendant Distributors of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating

> "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

741. As a result of the decade-long refusal by the Defendant Distributors to abide by federal law, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 177 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. The Drug Enforcement Administration's Adjudication of Registrant Actions, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014). The public record reveals many of these actions:

> On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (Orlando Facility) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;
>
> On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center (Auburn Facility) for failure to maintain effective controls against diversion of hydrocodone;
>
> On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (Lakeland Facility) for failure to maintain effective controls against diversion of hydrocodone;

On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center (Swedesboro Facility) for failure to maintain effective controls against diversion of hydrocodone;

On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center (Stafford Facility) for failure to maintain effective controls against diversion of hydrocodone;

On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (2008 MOA) with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility, and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Ohio (McDonough Facility), Valencia, California (Valencia Facility) and Denver, Colorado (Denver Facility);

On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (Lakeland Facility) for failure to maintain effective controls against diversion of oxycodone;

On June 11, 2013, Walgreens paid $80 million in civil penalties for dispensing violations under the CSA regarding the Walgreens Jupiter Distribution Center and six Walgreens retail pharmacies in Florida;

On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Sante Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA

742. Rather than abide by these public safety statutes, the Defendant Distributors, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[192]

FIRST CAUSE OF ACTION

CONSUMER SALES PRACTICES
CHAPTER 1345 OHIO REVISED CODE
(AGAINST ALL DEFENDANTS)

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

744. Defendants violated Chapter 1345. Of the Ohio Revised Code, because they engaged unfair and deceptive acts or practices and/or unconscionable consumer sales acts and practices in this state.

745. This Cause of Action is brought in the public interest under the Ohio Consumer Sales Practices Act ("CSPA"), R.C. 1345.01, *et seq.*, and seeks a declaratory judgment that Defendants have violated the CSPA, an injunction enjoining Defendants' misrepresentations described in this

[192] *See* Lenny Bernstein and Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic- grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.d84d374ef062; Lenny Bernstein and Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.b44410552cde.

Complaint, restitution to the County who on behalf of consumers paid for opioid prescriptions for chronic pain and therefore have been damaged by Defendants' conduct, and civil penalties. Between 2006 and 2016, Ohio consumers spent over $200 million on Defendants' opioids.

746. The CSPA prohibits, in connection with consumer transactions, unfair, deceptive or unconscionable consumer sales practices that mislead consumers about the nature of the product they are receiving. Specifically, the CSPA prohibits sellers from representing: that the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits that it does not have. R.C. 1345.02(B)(1).

747. In addition, Section 109:4-3-10 of the Ohio Administrative Code, interpreting the CSPA, makes it a deceptive act or practice for a supplier, in connection with a consumer transaction to "[m]ake any representations, claims, or assertions of fact, whether orally or in writing, which would cause a reasonable consumer to believe such statements are true, unless, at the time such representations, claims or assertions are made, the supplier possesses or relies upon a reasonable basis in fact such as factual, objective, quantifiable, clinical or scientific data or other competent or reliable evidence which substantiates such representations, claims, or assertions of fact."

748. Further, under R.C. 1345.07(A)(3)(c), the following acts are deemed to be deceptive pursuant to cases located within the Attorney General's Public Inspection File ("PIF"):

- Making any express or implied statement in connection with the marketing or advertisement of any product that is false, or has the capaCounty, tendency or effect of deceiving or misleading consumers; or omitting any material information such that the express or implied statement deceives or tends to deceive consumers. *State of Ohio ex rel. Rogers v. Airborne Health, Inc.*, Case No. 08-CVH-1217848 (Ct. Cmmn. Pleas, Franklin Cty).

- Making any representation, in connection with the marketing or advertising of a product, about research that has been performed, including but not limited to, any representation that a product has been clinically tested unless at the time the claim is made, competent and reliable scientific evidence exists substantiating such claim. *Airborne Health*.

- Making in connection with the marketing or advertising of a product. Any . . . statements or representations concerning a product that materially contradict or conflict with any other statements or representations the Defendants made about such Product and rend such statements or representations misleading and/or deceptive. *Airborne Health*.

- Making, or causing to be made, any written or oral claim that is false, misleading or deceptive. *State of Ohio ex rel. Michael DeWine v. Amgen Inc.*, Case No. 15CV7216 (Ct. Cmmn. Pleas, Franklin Cty).

- Representing that any product has any sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have. *Amgen Inc.*

- Representing that any product has any sponsorship, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have. *Amgen, Inc.*

- Making in a promotional context an express or implied representation, not approved or permitted for use in the labeling or under the FDCA, that a product is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by competent and reliable scientific evidence, whether or not such express or implied representation is made by comparison with another drug or treatment, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, a quotation, or other reference. *Amgen Inc.*

- Presenting information from a study in a way that implies that the study represents larger or more general experience with a product than it actually does. *Amgen Inc.*

- Misleadingly presenting favorable information or conclusion(s) from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusion(s) for information that may be material to an HCP prescribing decision when presenting information about a clinical study regarding a product. *Amgen Inc.*

- Making, or causing to be made, any written or oral claim, directly or by promotional speakers, that is false, misleading, or deceptive regarding any FDA approved product, including, but not limited to, any false, misleading, or deceptive claim when comparing the efficacy or safety of two products. *State of Ohio ex rel. Michael DeWine v. Pfizer Inc.*, Case No. 12 CV 15188 (Ct. Cmmn. Pleas, Franklin Cty.).

- Making any claim, directly or by promotional speakers, comparing the safety or efficacy of a product to another product when they claim is not supported by substantial evidence. *Pfizer Inc.*

- Making any claim, directly or by promotional speakers, that contradicts or minimizes a precaution, warning, or adverse reaction that is described in product labeling. *Pfizer Inc.*

749. As alleged herein, each Defendant, at all times relevant to this Complaint, violated the CSPA by making deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

750. Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to Oho consumers that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Exclusively disseminating misleading statements in education materials to Ohio hospital doctors and staff while purportedly educating them on new pain standards;

- Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to Ohio prescribers through in-person detailing; and

- Withholding from Ohio law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

751. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for highrisk patients;

- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for

the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to Ohio prescribers through in-person detailing.

752. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term

treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to Ohio prescribers through in-person detailing.

753. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

- Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

- Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to Ohio prescribers through in-person detailing and speakers bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to Ohio prescribers through in-person detailing and speakers bureau events.

754. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to Ohio prescribers through in-person detailing;
- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic noncancer pain and that opioids improve quality of life;

- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

755. These deceptive representations and concealments were reasonably calculated to deceive the County and County consumers, were made with the intent to deceive the State and Ohio consumers, and did in fact deceive the County and County consumers, who paid for prescription opioids for chronic pain.

756. As described more specifically above, Defendants' representations and concealments constitute a course of conduct which continues to this day.

757. But for these deceptive representations and concealments of material fact, County consumers would not have incurred millions of dollars in overpayments.

758. As a direct and proximate cause of Defendants' deceptive conduct, County consumers have been injured in an amount to be determined at trial.

759. Plaintiff and its residents have been injured by reason of Defendants' violation of chapter 1345 of the Ohio Revised Code.

SECOND CAUSE OF ACTION

DECEPTIVE TRADE PRACTICES CHAPTER 4165 OHIO REVISED CODE (AGAINST ALL DEFENDANTS)

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

761. Defendants violated Chapter 4165 of the Ohio Revised Code, because they engaged in deceptive trade practices in this state.

762. Plaintiff and its residents have been injured by reason of Defendants' violation of Chapter 4165 of the Ohio Revised Code.

THIRD CAUSE OF ACTION

PUBLIC NUISANCE OHIO PRODUCT LIABILITY ACT ("PLA") OHIO REVISED CODE CHAPTER 2307.71 et seq. AND COMMON LAW (AGAINST ALL DEFENDANTS)

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

764. 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 Lorain by their production, promotion, and marketing of opioids for use by residents of Lorain .

765. Defendants' conduct is not insubstantial or fleeting. 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.

766. Defendants' conduct constitutes a public nuisance.

767. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents.

768. Plaintiff and its residents suffered special injuries distinguishable from those suffered by the general public.

FOURTH CAUSE OF ACTION

FRAUD
(AGAINST ALL DEFENDANTS)

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

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

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

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

773. Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions.

774. The Defendants' intentionally did not alter or correct the disseminated information they knew to be fraudulent.

775. By reason of their reliance on Defendants' misrepresentations and omissions of material fact Plaintiff and its residents suffered actual pecuniary damage.

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

FIFTH CAUSE OF ACTION

UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

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

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

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

780. Defendants have been unjustly enriched at the expense of Plaintiff.

SIXTH CAUSE OF ACTION

NEGLIGENCE
(AGAINST ALL DEFENDANTS)

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

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

783. Defendants breached this duty by failing to take any action to prevent or reduce the distribution of the opioids.

784. As a proximate result, Defendants and its agents have caused Lorain to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, the County has borne the massive costs of these illnesses and conditions by having to provide necessary medical care, facilities, and services for treatment of County residents.

785. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

786. Defendants were negligent in disclosing to Lorain suspicious orders for opioids pursuant to the aforementioned Ohio statutes.

787. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

788. Defendants are in a class of a limited number of parties that can legally distribute opioids, which places it in a position of great trust by the County.

789. The trust placed in Defendants by Lorain through the license to distribute opioids in Lorain creates a duty on behalf of Defendants to prevent diversion of the medications it supplies to illegal purposes.

790. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to the County and its residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

791. Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

792. Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution.

793. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

794. Defendants are in exclusive control of the management of the opioids it distributed to pharmacies and drug stores in Lorain.

795. Lorain is without fault and the injuries to the County and its residents would not have occurred in the ordinary course of events had Distributor Defendants used due care commensurate to the dangers involved in the distribution of opioids.

SEVENTH CAUSE OF ACTION

NEGLIGENCE PER SE
(AGAINST ALL DEFENDANTS)

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

797. Defendants have a duty to comply with the regulations of the Ohio Revised Code §§ 2925.02, 2925.03, 3767.01, 4729.35, and Ohio Administrative Code §§ 4729-9-12, 4729-9-28, are public safety laws. Each Defendant had a duty under, *inter alia*, these laws maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.

798. Defendants' violations of the law constitute negligence per se.

799. Defendants failed to comply with Ohio law.

800. In the instant case, Ohio law requires that the Defendants know their customers, which includes, an awareness of the customer base, knowledge of the average prescriptions filled each day, the percentage of controlled substances compared to overall purchases, a description of how the

dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes, and identification of physicians and bogus centers for the alleged treatment of pain that are the dispenser's most frequent prescribers.

801. Defendants have failed to diligently respond to the suspicious orders which Defendants have filled.

802. Defendants have failed to provide effective controls and procedures to guard against diversion of controlled substances in contravention of Ohio law.

803. Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base comprised of individuals who are themselves abusing and/or dealing prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted.

804. Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions for controlled substances and thereby creating and continuing addictions to prescription medications in this state.

805. Defendants have, by their acts and omissions, proximately caused and substantially contributed to damages to Lorain County by violating Ohio law, by creating conditions which contribute to the violations of Ohio laws by others, and by their negligent and/or reckless disregard of the customs, standards and practices within their own industry.

806. Lorain County has suffered and will continue to suffer enormous damages as the proximate result of the failure by Defendants to comply with Ohio law.

807. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

808. Defendants are in a class of a limited number of parties that can legally sell and distribute opioids, which places it in a position of great trust by the County.

809. The trust placed in Defendants by Lorain County through the license to distribute opioids in Lorain County creates a duty on behalf of Defendants to prevent diversion of the medications it supplies to illegal purposes.

810. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to the County and its residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

811. Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

812. Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution.

813. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

814. Defendants are in exclusive control of the management of the opioids it distributed to pharmacies and drug stores in Lorain County.

815. Lorain County is without fault and the injuries to the County and its residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the distribution of opioids.

816. The harm that has occurred is the type of harm the above referenced Ohio laws were intended to guard against.

817. Defendants breached this duty by failing to take any action to prevent or reduce the distribution of the opioids.

818. As a direct and proximate result of Defendants' negligence per se, the County has suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for County Residents and using County resources in relation to opioid use and abuse.

819. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

820. Defendants were negligent in failing to monitor against diversion of opioid pain medications.

821. Plaintiff is entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

EIGHTH CAUSE OF ACTION

NEGLIGENT MARKETING
(AGAINST ALL DEFENDANTS)

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

823. Defendants had a duty to exercise reasonable care in the marketing of opioids.

824. Defendants were aware of the potentially dangerous situation involving opioids.

825. Defendants marketed opioids in an improper manner by:

a. overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;

b. trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose, and death;

c. overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;

d. mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms;

e. marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

826. It was Defendants' marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

827. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

828. Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which

exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

829. Defendants knew or should have known that opioids were unreasonably dangerous and could cause addiction.

830. Defendants' marketing was a factor in physicians, patients, and others to prescribe or purchase opioids.

831. As a direct and proximate result of Defendants' negligence, the County has suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for County Residents and using County resources in relation to opioid use and abuse.

832. Plaintiff is entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

NINTH CAUSE OF ACTION

OHIO CORRUPT PRACTICES ACT
OHIO REVISED CODE, §§ 2923.31, *et seq.*
(AGAINST ALL DEFENDANTS)

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

834. Defendants each operated an enterprise, for purposes that the illegal distribution of opioids for chronic pain. As explained herein, each Defendant conduct involves the commission of criminal offenses; the prohibited criminal conduct constitutes a pattern of corrupt activity; and each Defendant participated in the affairs of an enterprise and acquired and maintained control of an

enterprise. *See Universal Coach, Inc. v. New York lori Transit Auth., Inc.*, 629 N.E.2d 28, 32 (Ohio Ct. App. 1993)(cit. om.).

835. The defendants are persons within the meaning of Ohio Revised Code Section 2923.31(G) whom conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of Chapter 2923.

836. The County is a person as defined in Ohio Revised Code Section 2923.31(G).

837. The County was injured in its business or property as a result of the Defendants' wrongful conduct.

838. Pursuant to Ohio Rev. Code Ann. § 2923.34(A), the County has a claim for damages due to the wrongful conduct of the Defendants.

A. The Opioids Diversion Enterprise

839. Each Defendant formed an association-in-fact enterprise ("Opioids Diversion Enterprise"), and participated in the affairs of this enterprise when distributing highly dangerous, addictive opioid drugs in Lorain County. Each Defendant's Opioids Diversion Enterprise consists of (a) each Defendant, including its employees and agents; and (b) each Defendant's retail pharmacies which placed orders for vast quantities of opioids. Indeed, the Defendants could not have diverted opioids without the participation of retail pharmacies. The events described herein required retail pharmacies to place orders for these vast quantities of opioids.

840. Each Defendant and its respective pharmacy customers participated in the conduct of the Opioids Diversion Enterprise, sharing the common purpose of profiting from the sale of opioids, through a pattern of racketeering activity, which includes multiple violations of Ohio state criminal law and multiple instances of mail or wire fraud.

841. Each Defendant's Opioids Diversion Enterprise is an ongoing and continuing business organization that created and maintained systematic links for a common purpose: to profit from the

sale of opioid prescription pills. Each Defendant conducted this enterprise notwithstanding that its failure to abide by mandatory checks and balances constituted unlawful diversion of a dangerous controlled substance.

842. The system is structured such that manufacturers, wholesalers and pharmacies see greater profits at higher volumes. As a result, these companies are financially discouraged from undertaking efforts to combat opioid abuse. Wholesale Distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost ("WAC"). Discounts and rebates may be offered by the manufacturers based on, inter alia, market share and volume. Thus, the Defendant Wholesale Distributors are incentivized to order greater amounts so that they can decrease the cost per pill. The Defendant Wholesale Distributors used the decreased cost per pill to increase their market share (and thus, profits), by offering more competitive prices, or they maintained their prices and pocketed the difference as additional profit. Either way, increased sales volumes result in increased profits. At every turn, each Defendant maximized its profits through discounts and rebates by ordering and selling more opioids.[193]

843. As described above and expressly incorporated herein, the Defendant Wholesale Distributors: A) were placed on notice by the DEA, and were the subject of repeated DEA enforcement actions; and B) misrepresented their compliance with their legal obligations to maintain a closed system.

844. Each Defendant's Opioid Diversion Enterprise has caused opioids to be abused throughout Lorain County, with an ongoing cascade of human suffering and death that continues to consume the resources of the County's health and human services, health care, and law enforcement systems.

[193] "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," The Kaiser Family Foundation, March 2005.

845. Each Defendant and its respective retail pharmacy customers were willing participants in the Opioids Diversion Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose

B. Conduct of the Opioids Diversion Enterprise

846. To accomplish the common purpose of profiting from the sale of opioid prescription pills, each Defendant's Opioids Diversion Enterprise periodically and systematically misrepresented – either affirmatively or through half-truths and omissions – to the general public, the County, Ohio consumers, and the Ohio Board of Pharmacy, that it was fulfilling the requirements of its Ohio wholesale distributor license when, in fact, the duty to maintain effective controls to prevent diversion for non-medical purposes was being ignored in pursuit of ever increasing profits.

847. The persons engaged in each Defendant's Opioids Diversion Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities. Typically, this communication occurred, and continues to occur, through the use of the wires and mail in which each Defendant and its respective retail pharmacy customers communicate to facilitate the prescription opioid orders.

848. Each Defendant's Opioids Diversion Enterprise functions as a continuing unit for the purposes of profiting from the sale of opioid prescription drugs.

849. At all relevant times, the retail pharmacy customers were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct.

850. The sheer volume of prescription opioids flooding out of the doors of the Defendants and into communities across the country, including Lorain County, shocks the conscience and required each Defendant to take appropriate action, such as investigating such as investigating and reporting the

orders as suspicious. Given their place in the supply chain, the Defendants are uniquely situated to identify suspicious transactions. However, determined to increase their revenues, each of the Defendants willfully ignored obvious warning signs concerning suspicious orders. It would be virtually impossible for all of the orders to be legitimate, as there was no medical-need correlation justifying the skyrocketing orders for these addictive drugs.

851. For all times relevant to this Complaint, each Defendant exerted control over its Opioids Diversion Enterprise and participated in the operation and management of the affairs of the Opioids Diversion Enterprise, directly or indirectly, in the following ways:

a. Defendants obtained a license from the Ohio Board of Pharmacy but, contrary to the requirements of Ohio law, including federal laws incorporated by reference into Ohio law, Defendants failed to take necessary action to maintain effective controls against diversion of dangerously addictive prescription opioids, and in dereliction of nondelegable duties, marketed, distributed, and sold opioid pills to their retail pharmacy customers notwithstanding that the increase and quantum of addictive drug orders raised serious red flags regarding the drugs' unlawful, non-medical use;

b. Defendants misrepresented their compliance with their legal obligations, making false assurances that their marketing, sales and distribution complied with the law, including without limitation the requirements of Ohio manufacturer and distributor licenses, when, in truth, Defendants sold all the opioids they could, for profit, and in violation of their legal duties to guard against diversion of prescription opioids for illicit purposes;

c. Defendants refused to heed the DEA's warnings and continued to sell opioids and fill suspicious orders which were likely to be diverted;

d. Defendants refused to abide by the terms of DEA enforcement actions and settlements, continuing to sell opioids to market opioids and fill suspicious orders;

e. Defendants did not monitor, detect, investigate, refuse to fill, and report suspicious orders to the Ohio Board of Pharmacy as required under the terms of their licenses and applicable law;

f. Defendants intentionally and/or unlawfully sold the opioids unlawfully, purely for profit and without regard to the opioid plague, notwithstanding Defendants' knowledge that substantial foreseeable harm would occur;

g. Defendants only succeeded in these opioid sales by using wire and mail to communicate with physicians and retail pharmacies.

878. The defendants and retail pharmacies participated in each Defendant's Opioid Diversion Enterprise by employing mail and wire to send orders of opioids to Defendants and to buy opioids from Defendants. The retail pharmacies also participated in each Defendant's Opioid Diversion Enterprise by engaging with Defendants in violation of Ohio Revised Code § 2925.03(A), as described below.

879. The scheme devised and implemented by each Defendant, as well as other members of each Defendant's Opioids Diversion Enterprise, amounted to a common course of conduct intended to profit from Opioid sales.

C. Pattern of Racketeering Activity

880. Defendants conducted and participated in the conduct of the affairs of their respective Opioids Diversion Enterprise through a pattern of racketeering activity, which constitutes Corrupt Activity under Section 2923.31(I).

881. Regardless of any licenses or registrations held by Defendants to market, sell and distribute dangerous and harmful drugs, including opioids, their conduct was not "lawful." Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

882. The pattern of racketeering activity alleged herein and each Defendant's Opioids Diversion Enterprise are separate and distinct from each other. Likewise, each Defendant is distinct from the Opioids Diversion Enterprise.

883. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

884. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, Defendants' misrepresentations to the public, the Ohio Board of Pharmacy, and the DEA, depended on secrecy.

885. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including the County and its citizens. Defendants crafted the scheme to ensure their own profits remained high, without regard to the effect such behavior had on the County and its citizens. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the distribution chain and the Ohio Board of Pharmacy, inter alia, rely on the integrity of the Defendants to maintain a closed system and to protect against the non-medical uses of these dangerously addictive opioid drugs.

886. Defendants have knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including the distribution of dangerous and harmful drugs to persons, including minors, in violation of Ohio Revised Code Chapter 2925, at retail pharmacies, hospitals, and other health care facilities throughout Lorain County.

887. Defendants' actions were criminal and in violation of Ohio Revised Code Chapter 2925, and more specifically Section 2925.03(A), which forbids the distribution of controlled substances. Ohio Revised Code § 2925.03(A) states no person shall knowingly do any of the following:

> (1) Sell or offer to sell a controlled substance or a controlled substance analog;
>
> (2) Prepare for shipment, ship, transport, deliver, prepare for distribution, or distribute a controlled substance or a controlled substance analog, when the offender knows or has reasonable cause to believe that the controlled substance or a controlled substance analog is intended for sale or resale by the offender or another person.

OHIO REV. CODE ANN. § 2925.03(A) (1-2). The Defendants do not qualify for the Subsection (B) exception because Defendants' conduct was not in accordance with Chapter 4729, including code Ohio Revised Code Section 4729.35. Because Defendants failed to report suspicious sales, among other wrongful conduct described herein, their conduct is not in compliance, thereby stripping them of the Subsection (B) exception. See OHIO ADMIN. CODE § 4729-9-16(H)(1)(e)(i) ("The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns."). Any violation of Section 2925.03 is defined as "racketeering activity." OHIO REV. CODE ANN. § 2923.31(I)(2)(c).

888. Defendants have knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including thousands of separate instances of use of the United States Mail or interstate wire facilities in furtherance of the unlawful Opioids Diversion Enterprise. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering

activity. Defendants specifically intended to obtain money by means of false pretenses, representations, and promises, and used the mail and interstate wires for the purpose of executing this scheme; specifically, the Defendants communicated with physicians and their retail pharmacy customers via wire and used the mail to receive orders and sell drugs unlawfully. Any violation of the mail or wire fraud statutes is defined as "racketeering activity." OHIO REV. CODE ANN. § 2923.31(I)(1) (incorporating 18 U.S.C.A. § 1961(1)(B), which includes mail and wire fraud).

D. Damages

889. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused the County and its citizens to be injured in their business or property because the County has paid for costs associated with the opioid epidemic, as described above and expressly incorporated herein by reference.

890. The County's injuries, and those of her citizens, were proximately caused by Defendants' racketeering activities. But for Defendants' conduct, the County would not have paid the health services, law enforcement services, social services, and other expenditures required by the plague of drug-addicted residents.

891. The County's injuries, and those of her citizens, were directly caused by Defendants' racketeering activities.

892. The County was most directly harmed, and there is no other Plaintiff better situated to seek a remedy for the economic harms at issue here.

893. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia actual damages, treble damages, equitable relief, a civil penalty of up to one hundred thousand dollars, attorney fees and costs (OHIO REV. CODE ANN. § 2923.34), and/or pre- and postjudgment interest; however, notwithstanding any other statement in this Complaint, the County does not seek relief under Ohio Revised Code § 2923.34(B)(3), (4), or (5).

TENTH CAUSE OF ACTION

INJURY THROUGH CRIMINAL ACTS
OHIO REVISED CODE § 2307.60

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

895. Ohio Revised Code § 2307.60(A)(1), "by its plain and unambiguous terms, creates a statutory cause of action for damages resulting from any criminal act," unless otherwise prohibited by law. Jacobson v. Kaforey, 75 N.E.3d 203, 206 (Ohio 2016). "Anyone injured … by a criminal act has … a civil action" unless a civil action "is specifically excepted by law." OHIO REV. CODE ANN. § 2307.60(A)(1).

896. As described above in language incorporated herewith by reference, Lorain County has been injured by the Defendants' actions causing the opioid epidemic

897. Lorain County has sustained economic injuries and injuries to its property as a result of Defendants' actions, omissions, and unlawful conduct.

898. Said actions and omissions were criminal and in violation of Ohio Revised Code Chapter 2925, and more specifically Section 2925.03(A), which forbids the distribution of controlled substances. Defendants also sold drugs unlawfully pursuant to Ohio Revised Code §§ 4729.28, 4729.99(B).

899. In addition, under Ohio law it is unlawful to "[b]y any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent." OHIO REV. CODE ANN. § 2925.02(A)(3). The exemption in this statute only applies when the drug wholesaler's "conduct is in accordance with Chapter[]. . . 4729. . . of the Revised Code." OHIO REV. CODE

ANN. § 2925.02(B). Because Defendants failed to inter alia report suspicious sales, their conduct is not in compliance, and Defendants have thereby forfeited the protection provided by the exception. See OHIO ADMIN. CODE § 4729-9-16.

900. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia injunctive relief, full compensatory and punitive or exemplary damages, and all damages allowed by law to be paid by the Defendant Wholesale Distributors, attorney fees and costs, and pre- and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants, jointly and severally, as to all Causes of Action, awarding Plaintiff in amounts likely to exceed $25,000:

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

ii. treble damages, penalties and costs pursuant to Ohio Revised Code Sections 1345.09(B));

iii. Punitive Damages;

iv. Interest, Costs and Disbursements;

v. Imposition of an award of actual and triple the actual damages the County has sustained as a result of Defendants' violation of the Ohio Corrupt Practices Act;

vi. That Defendants be ordered to abate the public nuisance they created in violation of Ohio law;

vii. Such and further relief as this Court may deem just and proper;

JURY DEMAND

Plaintiff demands a trial by jury on all claims to the maximum number of jurors permitted by law.

Dated: December 11th, 2017
Cleveland, Ohio

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