**UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF TENNESSEE**

CANNON COUNTY, TENNESSEE,

Plaintiff,

vs.

PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., ALLERGAN PLC f/k/a ACTAVIS PLC, ALLERGAN FINANCE LLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., INSYS THERAPEUTICS, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, SPECGX LLC, CARDINAL HEALTH, INC., McKESSON CORPORATION, and AMERISOURCEBERGEN CORPORATION,

Defendants.

Case No.

**COMPLAINT AND JURY TRIAL DEMANDED**

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1. Plaintiff Cannon County brings this action against Defendants: Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Johnson & Johnson, Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Allergan PLC f/k/a Actavis PLC, Allergan Finance LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Insys Therapeutics, Inc., Mallinckrodt PLC, Mallinckrodt LLC, SpecGx LLC, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, to prevent future harm and to redress past wrongs. Plaintiff asserts two categories of claims: (1) claims against the pharmaceutical manufacturers of prescription opioid drugs that engaged in a massive false marketing campaign to drastically expand the market for such drugs and their own market share, and (2) claims against entities in the supply chain that reaped enormous financial rewards by refusing to monitor and restrict the improper distribution of those drugs.

2. Cannon County, Tennessee ("Cannon County" or the "County") is at the center of the opioid epidemic that plagues the nation. Cannon County is a vibrant, growing county in the Nashville Metropolitan Statistical Area. Because of its key location on a historically important highway, Cannon County, including its county seat, Woodbury, has served as a hub of commercial and artistic activity. Today, Cannon is recognized as an important regional center for folk decorative arts. Cannon also has a proud tradition of its citizens serving our country in the armed forces.

3. To care for and to protect the members of the community, Cannon County has unexpectedly had to spend funds on a wide range of services to fight the opioid epidemic's staggering, unanticipated, and far-reaching effects. The County does not have the resources to provide the range of services that it would like to provide to fight the opioid epidemic. As detailed herein, the opioid epidemic was caused by the malicious conduct of the Defendants motivated by the corporate need for ever greater profit. Cannon County brings this suit in order to force the Defendants to share in shouldering the costs with which they have burdened the County.

## INTRODUCTION

4. This case arises from the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.[1]

5. By now, most Americans have been affected, either directly or indirectly, by the opioid disaster. But few realize that this crisis arose from the opioid manufacturers' deliberately deceptive marketing strategy to expand opioid use, together with the distributors' equally deliberate efforts to evade restrictions on opioid distribution. Manufacturers and distributors alike acted without regard for the lives that would be trammeled in pursuit of profit.[2]

6. Since the push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, with no sign of slowing. The number of opioid overdoses in the United States rose from 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015.[3] In the twelve months that ended in September 2017, opioid overdoses claimed 45,000 lives.

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[1] Unless otherwise indicated, as used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

[2] *Overdose Death Rates*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (last updated Sept. 2017).

[3] *Understanding the Epidemic*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Aug. 30, 2017).

7. From 1999 through 2016, overdoses killed more than 350,000 Americans.[4] Over 200,000 of them, more than were killed in the Vietnam War, died from opioids prescribed by doctors to treat pain.[5] These opioids include brand-name prescription medications such as OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

8. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription opioids—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription opioids are 40 times more likely to become addicted to heroin. The Centers for Disease Control and Prevention ("CDC") has identified addiction to prescription opioids as the strongest risk factor for heroin addiction.

9. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

10. In the words of Robert Anderson, who oversees death statistics at the Centers for Disease Control and Prevention, "I don't think we've ever seen anything like this. Certainly not in modern times." On October 27, 2017, the President declared the opioid epidemic a public

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[4] *Prescription Opioid Overdose Data*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/overdose.html (last updated Aug. 1, 2017).
[5] *Examining the Growing Problems of Prescription Drug and Heroin Abuse* Ctrs. for Disease Control and Prevention (Apr. 29, 2014), http://www.cdc.gov.washington/testimony/2014/t20140429.htm; *see also*, Letter from Vivek H. Murthy, M.D., M.B.A., 19th U.S. Surgeon General, Turn the Tide RX (Aug. 2016), http://turnthetiderx.org.

health emergency.

11. This suit takes aim at the two primary causes of the opioid crisis: (a) a marketing scheme based on the false and deceptive marketing of prescription opioids, which was designed to dramatically increase the demand for and sale of opioids and opioid prescriptions; and (b) a supply chain scheme, pursuant to which the various entities in the supply chain failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs.

12. On the demand side, the crisis was precipitated by the defendants who manufacture, sell, and market prescription opioids ("Marketing Defendants"). Through a massive marketing campaign premised on false and incomplete information, the Marketing Defendants engineered a dramatic shift in how and when opioids were prescribed by the medical community and used by patients. The Marketing Defendants relentlessly and methodically, but untruthfully, asserted that the risk of addiction was low when opioids were used to treat chronic pain, and overstated the benefits and trivialized the risk of the long-term use of opioids.

13. The Marketing Defendants' goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

14. The Marketing Defendants' push to increase opioid sales worked. Through their publications and websites, endless stream of sales representatives, "education" programs, and

other means, the Marketing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the United States nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the United States—enough to medicate every adult in America around the clock for a month.

15. Meanwhile, the Defendants made blockbuster profits. In 2012 alone, opioids generated $8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately $9.6 billion.

16. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, (together, "Defendants"), who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

17. From the day they made the pills to the day those pills were consumed in our community, these manufacturers have had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring doctors into prescribing their products by arguing, among other things, that no one should be in pain, the Marketing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the

Marketing Defendants caused their profits to soar as more and more people became dependent on opioids. Today, as many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in a primary care setting struggles with addiction. And as of 2017, overdose death rates involving prescription opioids were five times higher than they were in 1999.

18. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

19. As a direct and foreseeable result of Defendants' conduct, cities and counties across the nation, including Plaintiff, are now swept up in what the CDC has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[6] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

20. Thus, rather than compassionately helping patients in pain, this explosion in opioid use—and Defendants' profits—has come at the expense of patients and Plaintiff has caused ongoing harm and damages to Plaintiff. As the CDC director concluded in 2014: "We know of no other medication routinely used for a nonfatal condition that kills patients so

[6] *Id.*

frequently."[7]

21. Defendants' conduct in promoting opioid use has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction, overdose, and death from illicit drugs such as heroin. The costs are borne by Plaintiff and other governmental entities. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarcerations, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements, among others.

22. The burdens imposed on Plaintiff are not the normal or typical burdens of governmental programs and services. Rather, these are extraordinary costs and losses that are directly related to Defendants' illegal actions. The Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

23. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis.

24. Within the next hour, six Americans will die from opioid overdoses; two babies will be born dependent on opioids and begin to go through withdrawal; and drug manufacturers will earn over $2.7 million from the sale of opioids.

25. Cannon County has filed this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

[7] *Id.*

## JURISDICTION AND VENUE

26. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 based on the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, et seq. ("RICO").

27. In addition, federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332, in that in each of the constituent actions there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and Defendants.

28. This Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in the State of Tennessee, purposefully directed their actions toward Tennessee, consensually submitted to the jurisdiction of Tennessee when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Tennessee necessary to constitutionally permit the Court to exercise jurisdiction.

29. Venue is proper in this District under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gives rise to the claim of relief in this District. Moreover, Plaintiff Cannon County is located in this District, and a substantial part of property that is the subject of this action is situated in this District.

## PARTIES

### I. PLAINTIFF

30. Cannon County, Tennessee, is located within the Middle District of Tennessee. Its total population is 13,801, according to 2010 U.S. Census Bureau statistics. Its county seat is

Woodbury, Tennessee.

31. Mike Gannon is the County Executive of Cannon County. The policy making and legislative authority is vested in a Board of County Commissioners consisting of ten members. The Chair of the Board of County Commissioners is Mark Barker.

32. Cannon County has the authority under the laws of the State of Tennessee to bring this lawsuit.

33. Cannon County is at the center of a rising opioid epidemic in Tennessee.

34. According to the Centers for Disease Controls, in recent years, the number of opioid prescriptions in Cannon County has consistently exceeded 1 prescription for each man, woman, and child in Cannon County, inflating at times to almost 1.3 prescriptions for each person in Cannon County. The opioid prescription rate in Cannon County has been at times in recent years more than 80% higher than the national average.

35. Cannon County funds emergency and ambulance services for its residents and has seen a substantial increase in the amount of emergency services needed due to opioid-related events.

36. Cannon County has been forced to spend substantial amounts of money on "Narcan" and other medication designed to treat opioid overdoses and abuse in the County for its emergency services and other programs.

37. The County has increased expenditures on juvenile and probation services and court matters due to the rising opioid epidemic.

38. Cannon County has suffered by being required to spend increasing amounts of money and resources to combat the increasing opioid epidemic over the past decade.

39. Cannon County has expended its taxpayers' resources to deal with each of the

aforementioned situations caused by the opioid epidemic, as well as many others.

40. Cannon County lacks resources it needs to address the opioid epidemic plaguing its county.

## II. Defendants

### A. Marketing Defendants.

41. At all relevant times, the Marketing Defendants each of whom is defined below, have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Marketing Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

#### 1. Purdue Entities

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

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

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

| Product Name | Chemical Name | Schedule[8] |
|---|---|---|
| OxyContin | Oxycodone hydrochloride, extended release | Schedule II |
| MS Contin | Morphine sulfate, extended release | Schedule II |
| Dilaudid | Hydromorphone hydrochloride | Schedule II |
| Dilaudid-HP | Hydromorphone hydrochloride | Schedule II |
| Butrans | Buprenorphine | Schedule III |
| Hysingla ER | Hydrocodone bitrate | Schedule II |
| Targiniq ER | Oxycodone hydrochloride and naloxone hydrochloride | Schedule II |

45. Purdue made thousands of payments to physicians nationwide, including in Tennessee, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

46. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin (launched in 1996) went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

47. 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

[8] Since passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs; hydrocodone and tapentadol were recently reclassified from Schedule III to Schedule II. Schedule II drugs have a high potential for abuse, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

**2. Actavis Entities**

48. 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 January 2013. Defendant Actavis, Inc. was acquired by Watson Pharmaceuticals, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. Defendant 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 (Allergan Finance LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants and entities is owned by Defendant Allergan PLC, which uses them to market and sell its drugs in the United States. Collectively, these defendants and entities, and their DEA registrant subsidiaries and affiliates which manufacture, promote, distribute, and sell prescription opioids, are referred to as "Actavis."

49. Actavis manufactures or has manufactured the following drugs as well as generic versions of Kadian, Duragesic, and Opana in the United States:

| Product Name | Chemical Name | Schedule |
|---|---|---|
| Kadian | Morphine sulfate, extended release | Schedule II |
| Norco | Hydrocodone bitartate and acetaminophen | Schedule II |

50. Actavis made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

### 3. Cephalon Entities

51. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation (collectively "Teva").

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

53. Teva USA and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids including the following:

| Product Name | Chemical Name | Schedule |
|---|---|---|
| Actiq | Fentanyl citrate | Schedule II |
| Fentora | Fentanyl buccal | Schedule II |

54. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Tennessee, many of whom were not oncologists and did not treat cancer pain, ostensibly for activities including participating on speakers' bureaus, providing consulting

services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

**4. Janssen Entities**

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

56. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen's products. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

57. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

58. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

59. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

60. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica and their DEA registrant subsidiaries and affiliates (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in Tennessee. Among the drugs Janssen manufactures or manufactured are the following:

| Product Name | Chemical Name | Schedule |
|---|---|---|
| Duragesic | Fentanyl | Schedule II |
| Nucynta[9] | Tapentadol hydrochloride, immediate release | Schedule II |
| Nucynta ER | Tapentadol hydrochloride, extended release | Schedule II |

61. Janssen made thousands of payments to physicians nationwide, including upon information and belief in Tennessee, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

62. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

63. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates,"

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

including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

64. J&J made payments to thousands of physicians nationwide, including in Tennessee, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

65. Information from the U.S. Department of Justice's Office of the Inspector General shows that J&J made payments to prescribers, but does not indicate which drug was being promoted when J&J made these payments. At least one prescriber who previously served on Janssen's speakers' bureau received payment for speaking fees, meals, and travel from J&J. Upon information and belief, J&J would have similarly made payments to other participants in Janssen's speaker's bureau.

**5. Endo Entities**

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

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

68. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place

of business located in Chestnut Ridge, New York. (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively "Par Pharmaceutical") Par Pharmaceutical was acquired by Endo International plc. in September 2015 and is an operating company of Endo International plc.

69. EHS, EPI, and Par Pharmaceutical, (collectively, "Endo") manufacture opioids sold nationally, and in Cannon County. Among the drugs Endo manufactures or manufactured are the following:

| **Product Name** | **Chemical Name** | **Schedule** |
|---|---|---|
| Opana ER | Oxymorphone hydrochloride, extended release | Schedule II |
| Opana | Oxymorphone hydrochloride | Schedule II |
| Percodan | Oxymorphone hydrochloride and aspirin | Schedule II |
| Percocet | Oxymorphone hydrochloride and acetaminophen | Schedule II |
| Generic | Oxycodone | Schedule II |
| Generic | Oxymorphone | Schedule II |
| Generic | Hydromorphone | Schedule II |
| Generic | Hydrocodone | Schedule II |

70. Endo made thousands of payments to physicians nationwide, including in Tennessee, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

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

72. The Food and Drug Administration requested that Endo remove Opana ER from

the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.[10]

### 6. Insys Therapeutics, Inc.

73. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys's principal product and source of revenue is Subsys:

| Product Name | Chemical Name | Schedule |
|---|---|---|
| Subsys | Fentanyl | Schedule II |

74. Insys made thousands of payments to physicians nationwide, including in Tennessee, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

75. Subsys is a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under-the-tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

76. In 2016, Insys made approximately $330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States, and in Tennessee.

77. Insys's founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Other Insys executives and managers were previously indicted.

### 7. Mallinckrodt Entities

78. Defendant Mallinckrodt plc is an Irish public limited company with its

[10] Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017).

headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly owned subsidiary of Mallinckrodt plc. Defendant Mallinckrodt LLC (together with Mallinckrodt plc and SpecGx LLC, "Mallinckrodt") is a Delaware corporation with its headquarters in Hazelwood, Missouri. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States, and in Cannon County. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

79. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

80. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received

approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[11]

81. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

82. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

| **Product Name** | **Chemical Name** | **Schedule** |
|---|---|---|
| Exalgo | Hydromorphone hydrochloride, extended release | Schedule II |
| Roxicodone | Oxycodone hydrochloride | Schedule II |
| Xartemis XR | Oxycodone hydrochloride and acetaminophen | Schedule II |
| Methadose | Methadone hydrochloride | Schedule II |
| Generic | Morphine sulfate, extended release | Schedule II |
| Generic | Morphine sulfate oral solution | Schedule II |
| Generic | Fentanyl transdermal system | Schedule II |
| Generic | Oral transmucosal fentanyl citrate | Schedule II |
| Generic | Oxycodone and acetaminophen | Schedule II |
| Generic | Hydrocodone bitartrate and acetaminophen | Schedule II |
| Generic | Hydromorphone hydrochloride | Schedule II |
| Generic | Hydromorphone hydrochloride, extended release | Schedule II |
| Generic | Naltrexone hydrochloride | unscheduled |
| Generic | Oxymorphone hydrochloride | Schedule II |

[11] Mallinckrodt plc, Annual Report (Form 10-K), 5 (Nov. 29, 2016), https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/0001567892-16-000098-index.htm.

| Product Name | Chemical Name | Schedule |
|---|---|---|
| Generic | Methadone hydrochloride | Schedule II |
| Generic | Oxycodone hydrochloride | Schedule II |
| Generic | Buprenorphine and naloxone | Schedule III |

83. Mallinckrodt made thousands of payments to physicians nationwide, including in Tennessee, ostensibly for activities including participating on speakers bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

84. Collectively, Purdue, Actavis, Cephalon, Janssen, Endo, Insys, and Mallinckrodt are referred to as "Marketing Defendants."[12]

### B. Distributor Defendants

85. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiff's community.

#### 1. Cardinal Health, Inc.

86. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Through its various DEA registered

[12] Together, Purdue, Cephalon, Janssen, Endo and Mallinckrodt are also sometimes referred to as "RICO Marketing Defendants."

subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

**2. McKesson Corporation**

87. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson, through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Plaintiff's community. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

88. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

**3. AmerisourceBergen Drug Corporation**

89. AmerisourceBergen Drug Corporation ("AmerisourceBergen"), through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Plaintiff's community. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in

Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

### C. Agency and Authority

90. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

## FACTUAL ALLEGATIONS

## III. FACTS COMMON TO ALL CLAIMS

### A. Opioids and Their Effects

91. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

92. The medicinal properties of opioids have been recognized for millennia—as well as their potential for abuse and addiction. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was with a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

93. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left

with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."[13]

94. Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

95. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

96. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

[13] Nick Miroff, *From Teddy Roosevelt to Trump: How Drug Companies Triggered an Opioid Crisis a Century Ago*, The Wash. Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca.

97. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

98. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

99. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents ("MME"). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

100. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

101. The wide variation in the MME strength of prescription opioids renders misleading any effort to capture "market share" by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total amount of MME in circulation, even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

102. Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50

times stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the market for opioids created by Marketing Defendants' promotion, with particularly lethal consequences.

103. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Insys's Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Marketing Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

104. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

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

anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

106. As a leading pain specialist doctor put it, the widespread, long-term use of opioids "was a de facto experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

## B. The Resurgence of Opioid Use in the United States

### 1. The Sackler Family Integrated Advertising and Medicine

107. Given the history of opioid abuse in the U.S. and the medical profession's resulting wariness, the commercial success of the Marketing Defendants' prescription opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

108. As it turned out, Purdue Pharma was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with a net worth of $13 billion as of 2016. The company's profits go to Sackler family trusts and entities.[14] Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

109. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company in 1952. It was Arthur Sackler who created the pharmaceutical advertising industry as we know it, laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

[14] David Armstrong, *The Man at the Center of the Secret OxyContin Files*, STAT News (May 12, 2016), https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/.

110. Arthur Sackler was both a psychiatrist and a marketing executive. He pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical education courses. He also understood the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.[15]

111. It was Arthur Sackler who, in the 1960s, made Valium into the first $100-million drug, so popular it became known as "Mother's Little Helper." When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called "psychic tension"—essentially stress—and pitched Valium as the solution.[16] The campaign, for which Arthur was compensated based on volume of pills sold,[17] was a remarkable success.

112. Arthur Sackler created not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which was distributed for free to doctors nationwide. Arthur also conceived a company now called IMS Health Holdings Inc., which monitors prescribing practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies like Marketing Defendants, who utilize it to target and tailor their sales pitches to individual physicians.

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[15] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204 (2003).
[16] *Id.* at 202; *see also One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23, 2017), http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids.
[17] Meier, *supra* note 18, at 201-203.

### 2. Purdue and the Development of OxyContin

113. After the Sackler brothers acquired the Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue, which would have been a conflict of interest. Raymond Sackler became Purdue's head executive, while Mortimer Sackler ran Purdue's UK affiliate.

114. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin, and it quickly became Purdue's bestseller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard had grand ambitions for the company; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big."[18] Richard believed Purdue should develop another use for its "Contin" timed-release system.

115. In 1990, Purdue's Vice President of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodeine," which also contributed to the

[18] Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/.

perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.[19]

116. For Purdue and OxyContin to be "*really* big,"[20] Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase.[21] As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

117. Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non-acute, everyday aches and pains. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."[22]

118. In pursuit of these 50 million potential customers, Purdue poured resources into

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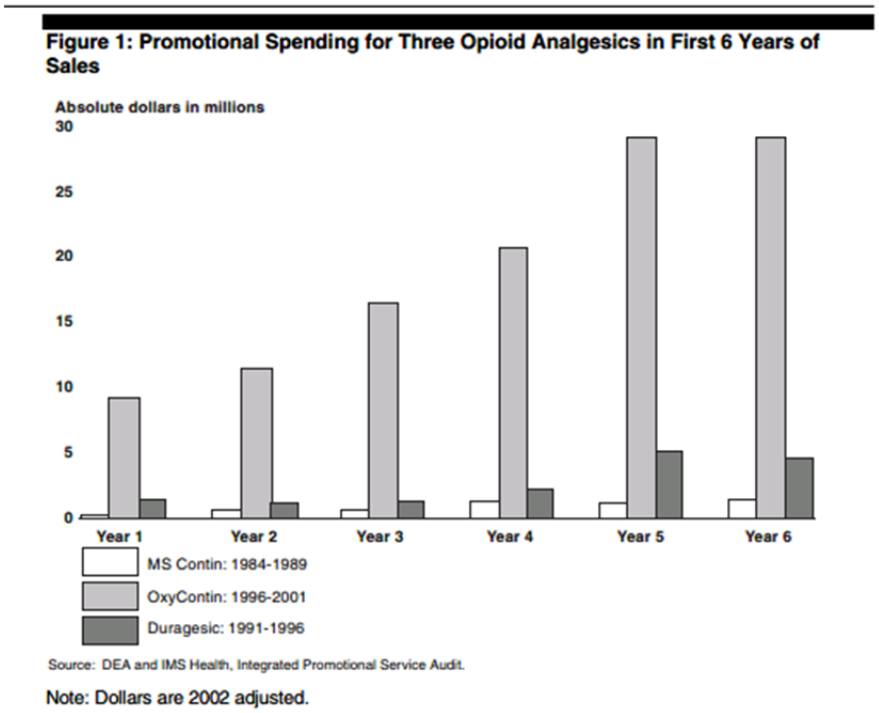
[19] *Id.*
[20] *Id.*
[21] Meier, *supra* note 18, at 269.
[22] *Id.*, at 156.

OxyContin's sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin or Defendant Janssen's spending on Duragesic: [23]




119. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

120. Purdue has generated estimated sales of more than $35 billion from opioids since 1996, raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue

[23] U.S. General Accounting Office, *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters, 22 (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.

proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

121. One might imagine that Richard Sackler's ambitions have been realized. But in the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits. Under the name of Mundipharma, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

122. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

> We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage. . . .
>
> Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .
>
> In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in

> the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.[24]

123. Purdue's recent pivot to untapped markets—after extracting substantial profits from American communities and leaving local governments to address the devastating and still growing damage the company caused—only serves to underscore that Purdue's actions have been knowing, intentional, and motivated by profits throughout this entire story.

### 3. Other Marketing Defendants Leapt at the Opioid Opportunity

124. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was not alone. The other Marketing Defendants—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in greater detail in Section D below.

125. Endo, which already sold Percocet and Percodan, was the first to submit an application for a generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended-release oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin's active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets

[24] Letter from Members of Congress to Dr. Margaret Chan, Director-General, World Health Organization (May 3, 2017), http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf.

proved highly susceptible to abuse. Called "blues" after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, "Drugs and Addict Lifestyle," Numorphan was extremely popular among addicts for its quick and sustained effect.[25] Endo withdrew oral Numorphan from the market in 1979.[26]

126. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and pushed it into the marketplace with a new trade name, Opana.

127. The clinical trials submitted with Endo's first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER in 2006.

128. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that this is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."[27] On July 6, 2017, Endo agreed to withdraw

[25] John Fauber & Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), https://www.medpagetoday.com/psychiatry/addictions/51448.
[26] *Id*.
[27] Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017). https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

Opana ER from the market.[28]

129. Janssen, which already marketed the Duragesic (fentanyl) patch for severe pain, also joined Purdue in pursuit of the broader chronic pain market. It sought to expand the use of Duragesic through, for example, advertisements proclaiming, "It's not just for end stage cancer anymore!"[29] This claim earned Janssen a warning letter from the FDA, for representing that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence."[30]

130. Janssen also developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of chronic pain in 2011.

131. By adding additional opioids or expanding the use of their existing opioid products, the other Marketing Defendants took advantage of the market created by Purdue's aggressive promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the $1 billion mark in sales of Duragesic in 2009.

### C. Defendants' Conduct Created an Abatable Public Nuisance

132. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance.

133. The public nuisance—*i.e.*, the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated by, *inter alia*, (a) educating prescribers (especially primary care physicians and the

[28] *Endo Pulls Opioid as U.S. Seeks to Tackle Abuse Epidemic*, Reuters (July 6, 2017, 9:59am), https://www.reuters.com/article/us-endo-intl-opana-idUSKBN19R2II.
[29] Letter from FDA to Janssen (March 30, 2000), at 2.
[30] *Id.*

most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

134. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well positioned to do so. It is the manufacturer of a drug that has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. And, all companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities exist independent of any FDA or DEA regulation, to ensure that their products and practices meet both federal and state consumer protection laws and regulations. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

### D. The Marketing Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception and Increase Demand for Opioids

135. In order to accomplish the fundamental shift in perception that was key to successfully marketing their opioids, the Marketing Defendants designed and implemented a sophisticated and deceptive marketing strategy. Lacking legitimate scientific research to support their claims, the Marketing Defendants turned to the marketing techniques first pioneered by Arthur Sackler to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

136. The Marketing Defendants promoted, and profited from, their misrepresentations

about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Marketing Defendants of these risks. The Marketing Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

137. The marketing scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Marketing Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these Defendants funded and controlled, "Front Groups," so-called industry "Key Opinion Leaders," and Continuing Medical Education ("CME") programs discussed subsequently below.

### 1. The Marketing Defendants Promoted Multiple Falsehoods About Opioids

138. The Marketing Defendants' misrepresentations fall into the following nine categories:

a. The risk of addiction from chronic opioid therapy is low

b. To the extent there is a risk of addiction, it can be easily identified and managed

c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids

d. Opioid withdrawal can be avoided by tapering

e. Opioid doses can be increased without limit or greater risks

f. Long-term opioid use improves functioning

g. Alternative forms of pain relief pose greater risks than opioids

h. OxyContin provides twelve hours of pain relief

i. New formulations of certain opioids successfully deter abuse

139. Each of these propositions was false. The Marketing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

140. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant.

**a. <u>Falsehood #1: The risk of addiction from chronic opioid therapy is low</u>**

141. Central to the Marketing Defendants' promotional scheme was the

misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

142. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

143. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose,"[31] and the risk substantially increases with more than three months of use. [32] As the CDC Guideline states, "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[33]

**i. Purdue's misrepresentations regarding addiction risk**

144. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its

[31] *FDA Announces Safety Labeling Changes and Postmarket Study Requirements For Extended-Release and Long-Acting Opioid Analgesics*, MagMutual (Aug. 18. 2016), https://www.magmutual.com/learning/article/fda-announces-safety-labeling-changes-and-postmarket-study-requirements-opioids; *see also* Press Release, U.S. Food & Drug Admin., FDA Announces Enhanced Warnings For Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose And Death, FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.
[32] Deborah Dowell, M.D. *et al*., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, 65(1) Morbidity & Mortality Wkly. Rep. 1, 21 (Mar. 18, 2016) (hereinafter "*CDC Guideline*").
[33] *Id.* at 2.

messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

145. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids.[34] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.

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.

146. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.[35]

[34] Jane Porter & Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Engl. J. Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[35] Meier, *supra* note 18, at 174.

147. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.[36] Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick.

148. Purdue specifically used the Porter and Jick letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos says "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*."[37] Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)"[38]

149. Other Marketing Defendants relied on and disseminated the same distorted messaging. The enormous impact of Marketing Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this

[36] Porter & Jick, *supra* note 37.
[37] Our Amazing World, *Purdue Pharma OxyContin Commercial*, Youtube (Sept. 22, 2016), https://www.youtube.com/watch?v=Er78Dj5hyeI.
[38] Patrick R. Keefe, *The Family That Built an Empire of Pain*, The New Yorker (Oct. 30, 2017) (hereinafter, "Keefe, *Empire of Pain*").

> citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .[39]

150. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[40]

151. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."[41]

152. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[42]

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[39] Pamela T.M. Leung, B.Sc. Pharm., *et al*., *A 1980 Letter on the Risk of Opioid Addiction*, 376 New Engl. J. Med. 2194, 2194–95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150.

[40] Marilynn Marchione, Associated Press, *Painful Words: How a 1980 Letter Fueled the Opioid Epidemic*, STAT News (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

[41] Press Release, Purdue Parma L.P., New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/.

[42] *Oxycontin: Its Use and Abuse: Hearing Before the House Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (Statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.

153. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain." In response to the question: "Aren't opioid pain medications like OxyContin Tablets 'addicting'?," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful. [43]

154. Sales representatives marketed OxyContin as a product "to start with and to stay with."[44] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!" [45] According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid." [46]

155. Purdue, through its unbranded website *Partners Against Pain*, stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids." "Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer

[43] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and a set of medical education resources distributed to prescribers by sales representatives, such as the brochure quoted here. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use.
[44] Keefe, *Empire of Pain, supra* note 41.
[45] Meier, *supra* note 18, at 102.
[46] *Id*.

pain."[47]

156. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."[48] May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

157. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

158. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

159. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

160. In the end, Purdue narrowed the recommended use of OxyContin to situations

[47] PURCHI 620694-723, at 700.

[48] Interview by Patrick Keefe with Steven Mays, former sales representative for Purdue Pharma L.P., *How Oxycontin Was Sold to the Masses*, The New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses.

when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially fatal dose." However, Purdue did not, until 2014, change the label as the FDA suggested, to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

**ii. Endo's misrepresentations regarding addiction risk**

161. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

162. Until April 2012, Endo's website for Opana, www.opana.com, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

163. Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo's training materials for its sales representatives in 2011 also prompted sales representatives to answer "true" to the statement that addiction to opioids is not common.[49]

164. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below. 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")[50] and its website

[49] ENDO-CHI_LIT-000059465-573, at 568.

[50] Endo was one of the APF's biggest financial supporters, providing more than half of the $10 million APF received from opioid manufacturers during its lifespan. Endo was the sole funder of NIPC and selected APF to manage NIPC. Internal Endo documents indicate that Endo was responsible for NIPC curriculum development, web posting, and workshops, developed and

www.Painknowledge.com, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

165. Another Endo website, www.PainAction.com, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

166. A brochure available on www.Painknowledge.com titled "*Pain: Opioid Facts*," Endo-sponsored NIPC stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message.

- In a patient education pamphlet titled "*Understanding Your Pain: Taking Oral Opioid Analgesics*," Endo answers the hypothetical patient question—"What should I know about opioids and addiction?"—by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." This publication is still available online.

167. An Endo publication, *Living with Someone with Chronic Pain*, stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com, until at least April 2012.[51]

168. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on www.Painknowledge.com, omitted addiction from the "common risks" of opioids, as shown below:

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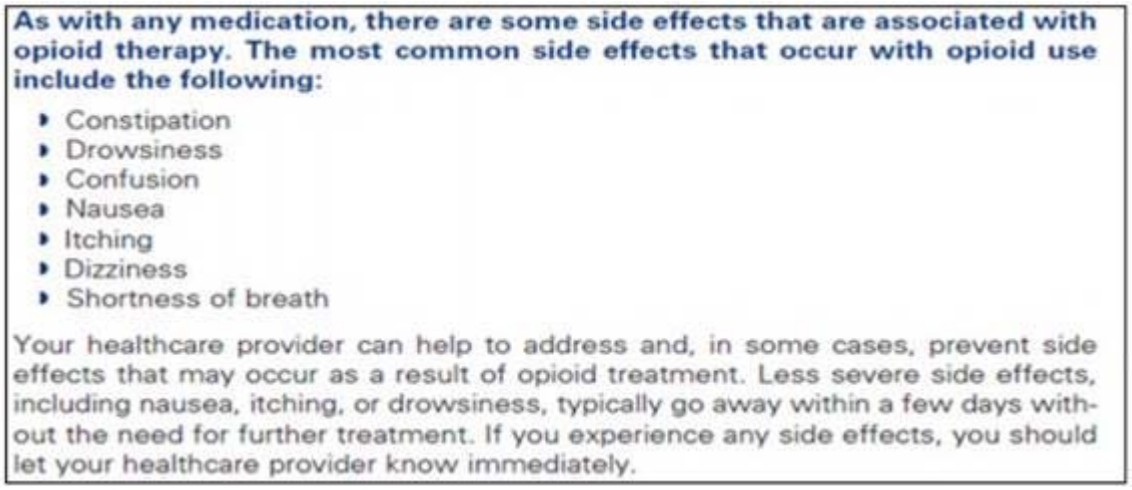
reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

[51] ENDO-CHI-LIT-00537916-922, at 921.



**As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:**

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

**iii. Janssen's misrepresentations regarding addiction risk.**

169. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction." (Although Janssen described the website internally as an unbranded third-party program, it carried Janssen's trademark and copy approved by Janssen.)

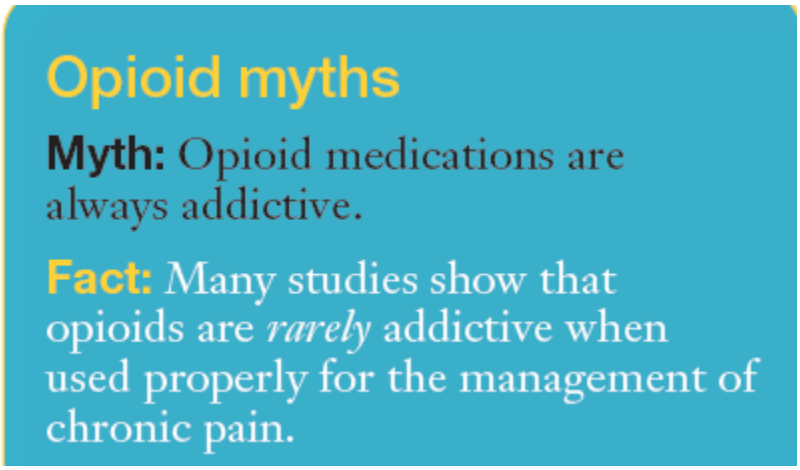
170. The *Let's Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which can be resolved with "effective pain management."

171. A Janssen unbranded website, www.PrescribeResponsibly.com, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[52]

172. Janssen reviewed, edited, approved, and distributed a patient education guide

[52] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last updated July 2, 2015).

entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Until recently, this guide was still available online.




173. Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "Addiction is relatively rare when patients take opioids appropriately."

**iv. Cephalon's misrepresentations regarding addiction risk.**

174. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, 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.

175. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[53]

**v. Actavis's misrepresentations regarding addiction risk.**

176. Through its "Learn More about customized pain control with Kadian," material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."[54]

177. Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (i) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.[55]

178. Actavis conducted a market study on takeaways from prescribers' interactions

[53] Michael J. Brennan, *et al*., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, http://www.medscape.org/viewarticle/449803 (behind paywall).
[54] ACTAVIS0006823-830, at 826.
[55] ACTAVIS0205095-286.

with Kadian sales representatives. The doctors had a strong recollection of the sales representatives' discussion of the low-abuse potential. Actavis' sales representatives' misstatements on the low-abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Actavis noted that doctors associate Kadian with less abuse and no highs, in comparison to other opioids.[56] Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.[57]

179. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state."[58] These statements convey both that (a) Kadian does not cause euphoria and therefore is less addictive and that (b) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

[56] *See* ACTAVIS0584610-649, at 628.
[57] S*ee* ACTAVIS0192847-78, at 49.
[58] ACTAVIS0947868-72, at 68-69.

### vi. Mallinckrodt's misrepresentations regarding addiction risk

180. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

181. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

182. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

- "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

183. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

184. Marketing Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

**b. <u>Falsehood #2: To the extent there is a risk of addiction, it can be easily identified and managed</u>**

185. While continuing to maintain that most patients can safely take opioids long-term

for chronic pain without becoming addicted, the Marketing Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

186. Purdue shared its *Partners Against Pain* "Pain Management Kit," which contains several screening tools and catalogues of Purdue materials, which included these tools, with prescribers. Janssen, on its website www.PrescribeResponsibly.com, states that the risk of opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors.[59] The website, which directly provides screening tools to prescribers for risk assessments,[60] includes a "[f]our question screener" to purportedly help physicians identify and address possible opioid misuse.[61]

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

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[59] Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids# (last modified July 2, 2015).

[60] *Risk Assessment Resources*, Prescribe Responsibly, http://www.prescriberesponsibly.com/risk-assessment-resources (last modified July 2, 2015).

[61] *Id.*

188. Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

189. Purdue sponsored a 2011 CME program titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

190. Purdue also funded 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, even high-risk patients showing signs of addiction could be treated with opioids.

191. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked to by Endo-supported websites, as well.

192. There are three fundamental flaws in the Marketing Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable

scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

**c. Falsehood #3: Signs of addictive behavior are "pseudoaddiction," requiring more opioids**

193. The Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term "pseudoaddiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[62] In other words, people on prescription opioids who exhibited classic signs of addiction— for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from undertreatment of their pain.

194. In the materials and outreach they produced, sponsored, or controlled, Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

195. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007) written by Dr. Fishman and discussed in more

[62] David E. Weissman & J. David Haddox, *Opioid Pseudoaddiction—An Iatrogenic Syndrome*, 36(3) Pain 363, 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565 ("Iatrogenic" describes a condition induced by medical treatment).

detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction."

196. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, www.PartnersAgainstPain.com, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudoaddiction" caused by untreated pain.

197. According to documents provided by a former Purdue detailer, sales representatives were trained and tested on the meaning of pseudoaddiction, from which it can be inferred that sales representatives were directed to, and did, describe pseudoaddiction to prescribers. Purdue's Pain Management Kit is another example of publication used by Purdue's sales force that endorses pseudoaddiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." Upon information and belief, the kit was in use from roughly 2011 through at least June 2016.

198. Similarly, internal documents show that Endo trained its sales representatives to promote the concept of pseudoaddiction. A training module taught sales representatives that addiction and pseudoaddiction were commonly confused. The module went on to state that: "The physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief."[63]

199. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction

[63] ENDO-CHI_LIT-000053284-335, at 299.

and listed "[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.[64]

200. Upon information and belief, Endo itself has repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the New York Attorney General, in a 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'"[65] Endo thereafter agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

201. Janssen sponsored, funded, and edited a website called *Let's Talk Pain*, which in 2009 stated "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is undertreated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until at least May 2012.

202. Janssen also currently runs a website, www.Prescriberesponsibly.com, which claims that concerns about opioid addiction are "overestimated," and describes pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately the

[64] ENDO-CHI_LIT-00179117-22, at 19.
[65] Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc.*, Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7.

inappropriate behavior ceases."[66]

203. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a KOL discussed below, admitted that pseudoaddiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."

**d. Falsehood #4: Opioid withdrawal can be avoided by tapering**

204. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering patients' dose to avoid withdrawal. Defendants failed to disclose the extremely difficult and painful symptoms that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for prolonged periods.

205. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

[66] Heit & Gourlay, *supra* note 59.

206. Purdue sponsored the APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

207. To this day, the Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

**e. Falsehood #5: Opioid doses can be increased without limit or greater risks**

208. In materials they produced, sponsored or controlled, Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Marketing Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

209. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose.

210. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of OxyContin."[67]

211. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

[67] Letter from Windell Fisher, Purdue Regional Manager, to B. Gergely, Purdue Employee (Nov. 7, 1996), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/ (last updated May 5, 2016) (hereinafter "Letter from Fisher").

> It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient them came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."
>
> The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

212. These misrepresentations were particularly dangerous. As noted above, opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

213. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[68]

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

215. Endo also published on its website a patient education pamphlet entitled

[68] Purdue Pharma L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf (last modified Nov. 2010).

*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 is, "The dose can be increased . . . You won't 'run out' of pain relief."

216. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pai*n (2007), which taught patients that opioids have "no ceiling dose" and therefore are safer than NSAIDs.

217. Marketing Defendants were aware of the greater dangers high-dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." For example, a study of patient data from the Veterans Health Administration published in 2011 found that higher maximum prescribed daily opioid doses were associated with a higher risk of opioid overdose deaths.[69]

**f. Falsehood #6: Long-term opioid use improves functioning**

218. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids as capable of improving patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

219. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork,

[69] Amy S. B. Bohnert, Ph.D. *et al*., *Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths*, 305(13) J. of Am. Med. Assoc. 1315, 1315-1321 (Apr. 6, 2011), https://jamanetwork.com/journals/jama/fullarticle/896182.

uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] . . . physical and social functioning."

220. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine…We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.[70]

221. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."[71]

222. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, "[f]or functional outcomes, the other analgesics

[70] Meier, *supra* note 18, at 281.
[71] Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, Wall St. J. (Jan. 23, 2003, 12:01am), https://www.wsj.com/articles/SB1043259665976915824.

were significantly more effective than were opioids."

223. A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

224. Similarly, since at least May of 2011, Endo has distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

225. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." 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. It assures patients that, "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'" Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

226. In addition, Janssen's *Let's Talk Pain* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

227. The APF's *Treatment Options: A Guide for People Living with Pain* (2007),

sponsored by Purdue and Cephalon, counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

228. Endo's NIPC website www.Painknowledge.com 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." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement.

229. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

230. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[72]

231. The Marketing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves

[72] Mallinckrodt Pharmaceuticals, *Responsible Use*, http://www.mallinckrodt.com/corporate-responsibility/responsible-use.

patients' function and quality of life.[73] Based upon a review of the existing scientific evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."[74]

232. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that [using] opioids for chronic pain may actually worsen pain and functioning,"[75] along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

233. The available evidence indicates opioids may worsen patients' health and pain. Increased duration of opioid use is also strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline

[73] The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[74] *CDC Guideline*, *supra* note 35, at 20.

[75] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. of Med., 1501, 1501-1502 (Apr. 21, 2016).

concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[76] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[77]

234. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as 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."[78] In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[79] Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.[80] Moreover, the first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications was recently published on March 6, 2018, in the Journal of the American Medical Association. The study reported that "[t]here was no significant difference in pain-

[76] *CDC Guideline*, *supra* note 35, at 2, 18.
[77] Frieden & Houry, *supra* note 86, at 1503.
[78] Andrea Rubinstein, M.D., *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.
[79] Jeffrey Dersh, *et al*., *Prescription Opioid Dependence Is Associated With Poorer Outcomes In Disabling Spinal Disorders*, 33(20) Spine 2219, 2219-27 (Sept. 15, 2008).
[80] GM Franklin, BD Stover *et al*., *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: The Disability Risk Identification Study Cohort*, 33(2) Spine 199, 201-202 (Jan. 15, 2008).

related function between the 2 groups" – those whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and other non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen. Accordingly, the study concluded: "Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."[81]

**g. Falsehood #7: Alternative forms of pain relief pose greater risks than opioids**

235. In materials they produced, sponsored or controlled, the Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

236. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Marketing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[82] hormonal dysfunction;[83] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[84] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol

[81] EE Krebs, *et al.*, *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial*, 319(9) J. Am. Med. Ass'n. 872 (Mar. 6, 2018).
[82] Letter from Janet Woodcock, M.D., Dir. of Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. of Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).
[83] H.W. Daniell, *Hypogonadism in Men Consuming Sustained-Action Oral Opioids*, 3(5) J. Pain 377, 377-84 (2001).
[84] Bernhard M. Kuschel, *The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People—a Swedish Case-Control Study*, 25(3) Eur. J. Pub. H. 527, 527-32 (July 31, 2014).

or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.[85]

237. The APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdoses, when the figure is closer to 3,200.[86]

238. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), that listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase 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.

239. Endo's NIPC website, Painknowledge.com, which contained a flyer called "*Pain: Opioid Therapy*." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

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[85] Karen H. Seal *et al*., *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. of Am. Med. Assoc. 940, 940-47 (2012).

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

240. As another example, the Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk of opioids, claiming opioids have "possibly less potential for abuse than in younger patients," and does not list overdose among the adverse effects. Some of those misrepresentations are described above; others are laid out below.

241. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[87] The article asserted:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[88]

242. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

243. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains

[87] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, https://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf.
[88] *Id.* at 1.

available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

244. As a result of the Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[89]

**h. Falsehood #8: OxyContin provides twelve hours of pain relief**

245. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provides the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

246. 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

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

the following chart, which was apparently adapted from Purdue's own sales materials:

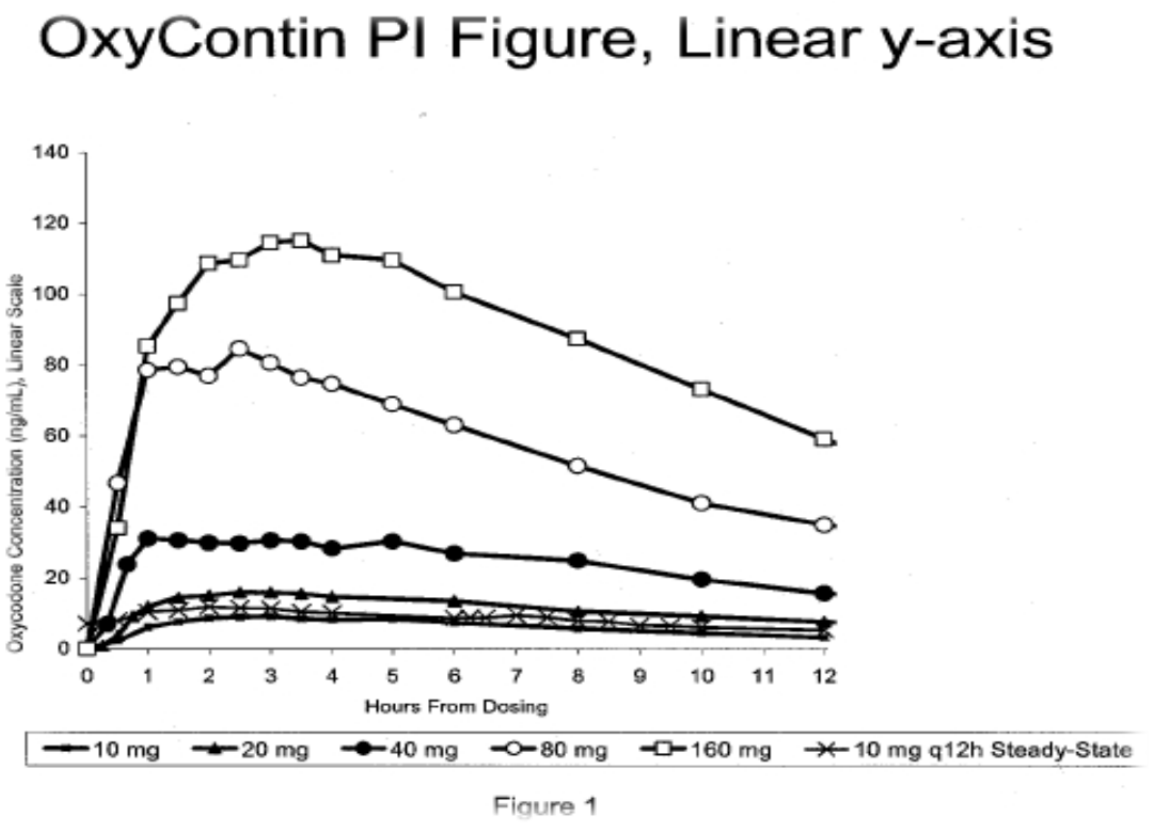



Figure 1

247. 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 twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

248. 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 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 twelve

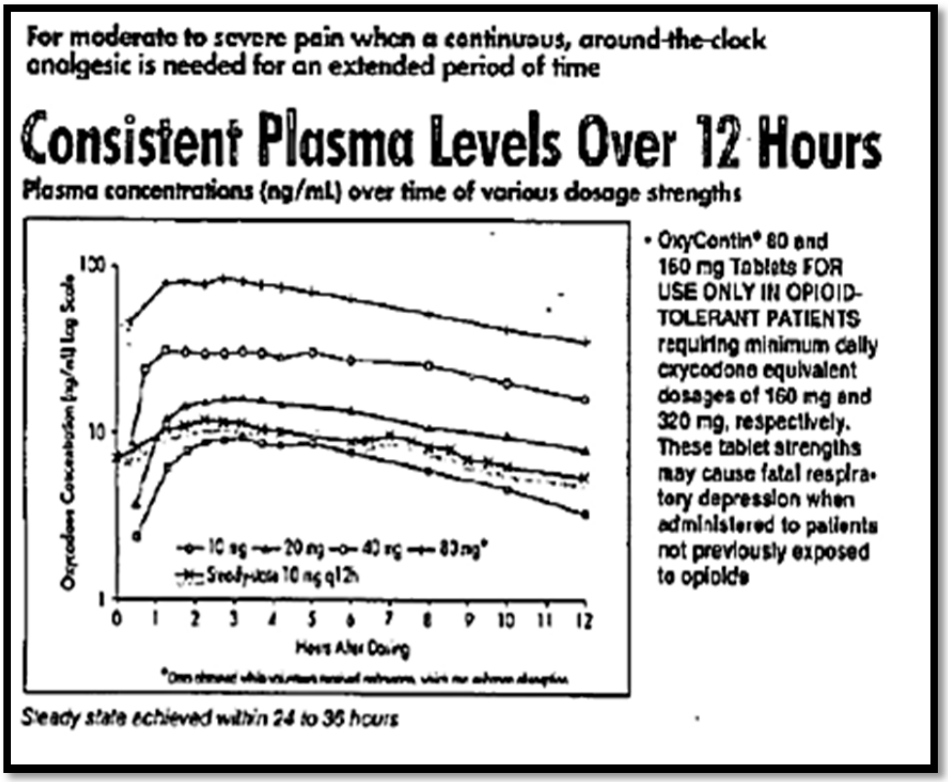
hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience end-of-dose failure with OxyContin.)

249. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[90] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

250. It was Purdue's decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," that is because Purdue has conducted no such studies.

251. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively 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:

[90] Harriet Ryan *et al*., "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," L. A. Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/ (hereinafter, "*You Want a Description of Hell*").




252. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" 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. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."[91]

253. In keeping with this positioning statement, a Purdue regional manager emphasized in a 1996 sales strategy memo that representatives should "convinc[e] the physician

[91] Memorandum from Lydia Johnson, Marketing Executive at Purdue, to members of Oxycontin Launch Team (Apr. 4, 1995), http://documents.latimes.com/oxycontin-launch-1995/ (last updated May 5, 2016).

that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses."[92] One sales manager instructed her team that anything shorter than 12-hour dosing "needs to be nipped in the bud. NOW!!"[93]

254. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. It also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[94]

255. That OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue's competitors, but was not disclosed to prescribers. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two was set out in Purdue's internal documents as early as 1999 and is apparent from MEDWATCH Adverse Event reports for OxyContin.

256. 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

[92] Letter from Fisher, *supra* note 67.
[93] *You Want a Description of Hell*, *supra* note 90.
[94] *CDC Guideline*, *supra* note 32, at 16.

12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

257. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue's competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

**i. Falsehood #9: New formulations of certain opioids successfully deter abuse**

258. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as a competitive opportunity. These companies developed and oversold "abuse-deterrent formulations" ("ADF") opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants' false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

259. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

### i. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER

260. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

261. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

262. Despite its self-proclaimed good intention, Purdue merely incorporated its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

- claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;
- claimed that Purdue's ADF opioids reduce opioid abuse and diversion;
- asserted or suggested that its ADF opioids are non-addictive or less addictive,
- asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and
- failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

263. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug, but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

264. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with and abused.

265. In 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

266. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to abuse OxyContin orally after the reformulation rather than shift to other drugs.

267. A 2013 article presented by Purdue employees based on review of data from poison control centers concluded that ADF OxyContin can reduce abuse, but it ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the

advantages and ignored the disadvantages of ADF OxyContin.

268. Websites and message boards used by drug abusers, such as www.bluelight.org and www.reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

269. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

270. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[95] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

271. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF

[95] Jill Hartzler Warner, Assoc. Comm'r for Special Med. Programs, *Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting*, 80(103) Fed. Reg. 30686, 30686 (May 29, 2015).

opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

**ii. Endo's deceptive marketing of reformulated Opana ER**

272. As the expiration of its patent exclusivity for Opana ER neared, Endo also made abuse-deterrence a key to its marketing strategy.[96]

273. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

274. Endo knew by July 2011 that "some newer statistics around abuse and diversion are not favorable to our product."[97]

275. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

276. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In

[96] ENDO-CHI_LIT-00141071.
[97] ENDO-CHI_LIT-00401875.

other words, Opana ER was still crushable. Indeed, Endo's own studies dating from 2009 and 2010 showed that Opana ER could be crushed and ground, and, in its correspondence with the FDA, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion overdose, or addiction."

277. Further, a January 4, 2011 FDA Discipline Review letter made clear to Endo that "[t]he totality of these claims and presentations suggest that, as a result of its new formulation, Opana ER offers a therapeutic advantage over the original formulation when this has not been demonstrated by substantial evidence or substantial clinical experience. In addition these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's "INTAC" technology confers some form of abuse-deterrence properties when this has not been demonstrated by substantial evidence."[98] The FDA acknowledged that while there is "evidence to support some limited improvement" provided by the new coating, but it would not let Endo promote any benefit because "there are several limitations to this data."[99] Also, Endo was required to add language to its label specifically indicating that "Opana ER tablets may be abused by crushing, chewing, snorting, or injecting the product. These practices will result in less controlled delivery of the opioid and pose a significant risk to the abuser that could result in overdose and death."[100]

278. The FDA expressed similar concerns in nearly identical language in a May 7, 2012 letter to Endo responding to a February 2, 2012, "request … for comments on a launch Draft Professional Detail Aid … for Opana ER." The FDA's May 2012 letter also includes a full two pages of comments regarding "Omissions of material facts" that Endo left out of the

[98] ENDO-CHI_LIT-00075639-45, at 40.
[99] *Id.*
[100] *Id.* at 39.

promotional materials.

279. Endo consciously chose not to do any post-approval studies that might satisfy the FDA. According to internal documents, the company decided, by the time its studies would be done, generics would be on the market and "any advantages for commercials will have disappeared."[101] However, this lack of evidence did not deter Endo from marketing Opana ER as ADF while its commercial window remained open.

280. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

281. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.[102] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than

[101] ENDO CHI LIG 65055-59, at 57

[102] Plf.'s Opp. to Defs.' and Intervenor's Motions to Dismiss and Plf's Reply in Supp. of Motion for Prelim. Inj. ("Endo Br.") [ECF No. 23], *Endo Pharms. Inc. v. U.S. Food and Drug Admin., et al.*, No. 1:12-cv-01936, at 20 (D.D.C. Dec.14, 2012).

protection of the public health."[103]

282. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[104]

283. In its citizen petition, Endo asserted that redesigned Opana ER CRF had "safety advantages." Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, "where children unintentionally chew the tablets prior to an accidental ingestion."[105]

284. However, in rejecting the petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

285. Meanwhile, in 2012, an internal memorandum to Endo account executives noted that abuse of Opana ER had "increased significantly" in the wake of the purportedly abuse-

[103] Defs.' Resp. to the Court's Nov. 30, 2012 Order [ECF No. 9], *Endo Pharms. Inc. v. U.S. Food and Drug Admin., et al.*, No. 1:12-cv-01936, at 6 (D.D.C. Dec. 3, 2012).
[104] *Id.*; Endo News Release, (Sept. 6, 2012) [ECF No. 18-4], *Endo Pharms. Inc. v. U.S. Food and Drug Admin., et al.*, No. 1:12-cv-01936 (D.D.C. Dec. 9, 2012), at 81.
[105] Citizen Petition, FDA Docket 2012-8-0895, at 5.

deterrent formulation. In February 2013, Endo received abuse data regarding Opana ER from Inflexxion, Inc., which gathers information from substance abusers entering treatment and reviews abuse-focused internet discussions, that confirmed continued abuse, particularly by injection.

286. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%. Endo's own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.[106] The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

287. Publicly, Endo sought to marginalize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

288. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. Upon information and belief, based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug,

[106] Theresa Cassidy *et al*., *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Pain Week Abstract 2014, https://www.painweek.org/assets/documents/general/724-painweek2014acceptedabstracts.pdf.

most would be protected.

289. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential." An internal Endo document also notes that market research showed that, "[l]ow abuse potential continues as the primary factor influencing physicians' anticipated increase in use of Opana ER over the next 6 months."[107]

290. In its written materials, Endo marketed Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually was crush-resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."

291. The press release further stated that: "We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers." The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

292. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in

[107] ENDO-CHI_LIT-00156509, at 97.

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 patients and prescribers.

293. Endo, upon information and belief, targeted particular geographies for the redesigned Opana ER where abuse was most rampant.[108]

294. In March 2017, because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.[109] Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.[110] However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it "has taken significant steps over the years to combat misuse and abuse."

**iii. Other Marketing Defendants' misrepresentations regarding abuse deterrence**

295. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and "KADIAN may be less likely to be abused by health care providers and illicit users" because of its "[s]low onset of action."[111] Kadian, however, was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

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[108] 118 ENDO-CHI_LIT-00054637, at 4.
[109] Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.
[110] Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.
[111] ACTAVIS0947868-72, at 68-69.

296. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[112] One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."[113]

297. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[114] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[115]

298. While Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

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[112] Press Release, Covidien, FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain (Aug. 27, 2012), http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159.

[113] Office of Senator Edward J. Markey, *"Abuse-Deterrent Opioid" is an Oxymoron*, Senator Ed Markey (Feb. 2016), https://www.markey.senate.gov/imo/media/doc/2016-02-19-Markey-ADF-Opioid-timeline.pdf.

[114] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

[115] Samantha Liss, *Mallinckrodt Banks on New Painkillers for Sales*, St. Louis Bus. J. (Dec. 30, 2013), http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/.

299. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was not supported by or was contrary to the scientific evidence. In addition, the misrepresentations and omissions set forth above and elsewhere in this Complaint are misleading and contrary to the Marketing Defendants' products' labels.

### 2. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels

300. The Marketing Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

301. The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Marketing Defendants; (2) so-called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Marketing Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives or "detailers"; and (8) speakers bureaus and programs.

#### a. The Marketing Defendants Directed Front Groups to Deceptively Promote Opioid Use

302. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for

chronic pain, overstated their benefits, and understated their risks.[116] 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—often at the expense of their own constituencies.

303. "Patient advocacy organizations and professional societies like the Front Groups 'play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.'"[117] "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[118] Indeed, the U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,[119] which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, "provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy,"[120] found that the Marketing Defendants made millions of dollars' worth of contributions to various Front Groups.[121]

304. The Marketing Defendants also "made substantial payments to individual group

[116] U.S. S. Homeland Sec. & Governmental Aff. Comm., Ranking Members' Office, *Fueling an Epidemic*, Feb. 12, 2018, https://www.hsdl.org/?view&did=808171 at 3 (hereinafter "*Fueling an Epidemic*").
[117] *Id*. at 2.
[118] *Id*.
[119] *Id.* at 3.
[120] *Id.* at 1.
[121] *Id*. at 3.

executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.[122]

305. As the Senate *Fueling an Epidemic* Report found, the Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[123] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC Guideline on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[124]

306. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each other to deceptively promote the use of opioids for the treatment of chronic pain.

**i. American Pain Foundation**

307. The most prominent of the Front Groups was the APF. While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Defendants Purdue, Endo, Janssen, and Cephalon. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming

[122] *Id*. at 10.
[123] *Id*. at 12-15.
[124] *Id*. at 12.

grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012.

308. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed below.

309. APF also developed the NIPC, which ran a facially unaffiliated website, www.painknowledge.com. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or www.painknowledge.org. Endo estimated it would reach 60,000 prescribers through NIPC.

310. APF was often called upon to provide "patient representatives" for the Marketing Defendants' promotional activities, including for Purdue's "Partners Against Pain" and Janssen's "Let's Talk Pain." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to

strategically align its investments in nonprofit organizations that share [its] business interests.

311. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

312. 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. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

313. APF's Board of Directors was largely comprised of doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Marketing Defendants demonstrates APF's clear lack of independence, in its finances, management, and mission, and its willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions. For example, a roundtable

convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence."

314. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

#### ii. American Academy of Pain Medicine and the American Pain Society

315. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[125] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's

[125] Consensus Statement by the Am. Acad. of Pain Med. & the Am. Pain Soc'y, *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf (August 18, 2017).

website.

316. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

317. Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[126]

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

319. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

320. AAPM's staff understood that they and their industry funders were engaged in a

[126] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Med., Chief of the Div. of Pain Med., Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829.

common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

321. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

322. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

323. 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 Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

324. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors

to whom Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."[127]

325. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

326. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

**iii. FSMB**

327. 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.

328. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

329. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled

[127] *CDC Guideline*, *supra* note 35, at 2.

Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

330. Both a 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, made the same claims as did the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Cannon County.

331. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.[128]

332. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline

[128] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (2007).

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

### iv. The Alliance for Patient Access

333. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[129] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[130] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes J&J, Endo, Mallinckrodt, Purdue and Cephalon.

334. APA's board members have also directly received substantial funding from pharmaceutical companies.[131] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from Defendants Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its

[129] *About AfPA*, The All. for Patient Access, http://allianceforpatientaccess.org/about-afpa (last visited Apr. 25, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[130] Mary Chris Jaklevic, *Non-Profit Alliance for Patient Access Uses Journalists and Politicians to Push Big Pharma's Agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ (hereinafter "Jaklevic, *Non-Profit Alliance for Patient Access*").

[131] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, https://projects.propublica.org/docdollars/.

payment of kickbacks to physicians who prescribed Subsys.[132] Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by Defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including Defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including Defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

335. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[133] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> * * *
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult

[132] Andy Marso, *FBI Seizes Records of Overland Park Pain Doctor Tied to Insys*, Kansas City Star (July 20, 2017), http://www.kansascity.com/news/business/health-care/article162569383.html.

[133] Pain Therapy Access Physicians Working Group, *Prescription Pain Medication: Preserving Patient Access while Curbing Abuse*, (Dec. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

> the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .
>
> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[134]

336. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[135]

337. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.[136]

338. In conclusion, the white paper states that "[p]rescription pain medications, and

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[134] *Id*. at 4-5.
[135] *Id.* at 5-6.
[136] *Id.* at 6.

specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[137]

339. The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA's agenda.[138]

340. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act"). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "could actually result in increased diversion, abuse, and public health and safety consequences"[139] and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the Defendants here, in the federal courts.[140] The bill passed both houses of

[137] *Id.* at 7.
[138] Jaklevic, *Non-Profit Alliance for Patient Access*, *supra* note 129.
[139] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry").
[140] John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. 333, 346 (2017).

Congress and was signed into law in 2016.

### v. The U.S. Pain Foundation ("USPF")

341. The USPF was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone.[141] The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[142] Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

### vi. American Geriatrics Society ("AGS")

342. The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate 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,[143]

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[141] *Fueling an Epidemic*, *supra* note 116, at 4.
[142] *Id*. at 12; *see also Transparency*, U.S. Pain Foundation, https://uspainfoundation.org/transparency/ (last visited Mar. 9, 2018).
[143] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf (last visited Apr. 25, 2018) (hereinafter "2009 AGS Guidelines").

hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009.[144] AGS's complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal 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 pro-opioid publications.

343. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.[145] These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

344. Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS 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.

345. Members of AGS Board of Directors were doctors who were on the Marketing

[144] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly, Milwaukee J. Sentinel* (May 30, 2012) https://www.medpagetoday.com/geriatrics/painmanagement/32967.
[145] 2009 AGS Guidelines, *supra* note 143, at 1342.

Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

### b. The Marketing Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use

346. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine, and Dr. Scott Fishman, as set forth below.

347. Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

348. As the Marketing Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

349. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive

their information.

350. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

351. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' agenda. The Marketing Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Marketing Defendants kept these KOLs well-funded to enable them to push the Marketing Defendants' deceptive message out to the medical community.

352. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

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

themselves and the Marketing Defendants.

**i. Dr. Russell Portenoy**

354. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[146]

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

> *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[147]

[146] R. Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).
[147] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[148]

356. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"[149]

357. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."[150]

358. Dr. Portenoy was also a critical component of the Marketing Defendants' control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

359. In recent years, some of the Marketing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific

[148] *Id.*
[149] Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* 314 (Bloomsbury Press 2015).
[150] *Id.* at 136.

literature.[151] Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[152] He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."[153]

360. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*[154]

361. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."[155]

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[151] *See, e.g.*, John Fauber, *Painkiller Boom Fueled by Networking*, Journal Sentinel (Feb. 18, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/ (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

[152] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall St. J., https://www.wsj.com/articles/SB10001424127887324478304578173342657044604. (Last updated Dec. 17, 2012, 11:36 AM)

[153] *Id*.

[154] Harrison Jacobs, *This 1-Paragraph Letter May Have Launched the Opioid Epidemic*, AOL (May 26, 2016, 1:39 PM), https://www.aol.com/article/2016/05/26/letter-may-have-launched-opioid-epidemic/21384408/; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be.

[155] Meier, *supra* note 18, at 277.

### ii. Dr. Lynn Webster

362. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo's 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).

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

364. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids:

he prescribed staggering quantities of pills.

365. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP." This CME effectively amounted to off-label promotion of Cephalon's opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.

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

**iii. Dr. Perry Fine**

367. Dr. Perry Fine's ties to the Marketing Defendants have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as

treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.[156]

368. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.

369. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from J&J for providing "educational" services, but J&J's website states that the company paid him $32,017 for consulting, promotional talks, meals and travel that year.[157]

370. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

> At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.
>
> Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.[158]

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[156] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true. (hereinafter, "Fishman").

[157] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14 AM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter, "Weber").

[158] Perry G. Fine & Russell K. Portenoy, *A Clinical Guide to Opioid Analgesia*, McGraw-Hill Companies, 2004, at 20, 34. http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

371. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[159] In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[160]

372. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."[161]

373. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches

[159] Perry G. Fine *et al*., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Mgmt. 747-60 (Nov. 2010).
[160] *Id*. at 748.
[161] *Id*. at 759.

over a person's "lifetime" to manage pain.[162] He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*." The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[163]

**iv. Dr. Scott Fishman**

374. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[164]

375. Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing," in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

376. In 2012, Dr. Fishman updated the guide and continued emphasizing the

[162] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.
[163] *Id.*
[164] Fishman, *supra* note 156; *see also* Weber, *supra* note 157.

"catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.[165]

377. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."[166]

378. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[167] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

### c. The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs

379. Now that the Marketing Defendants had both a group of physician promoters and had built a false body of "literature," Defendants needed to make sure their false marketing message was widely distributed.

380. One way the Marketing Defendants aggressively distributed their false message was through thousands of Continuing Medical Education courses ("CMEs").

381. A CME is a professional education program provided to doctors. Doctors are

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[165] Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences, 2d ed. 2012).
[166] *Id.*
[167] Scott M. Fishman, *Listening to Pain: A Clinician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

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

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

383. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

384. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

385. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex

pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[168] The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

386. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

387. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Scott Fishman.

388. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

389. The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs creates; stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests

[168] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale with Opioids*, Medscape (Sept. 16, 2003), http://www.medscape.org/viewarticle/461612.

could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[169]

390. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

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

#### d. The Marketing Defendants Used "Branded" Advertising to Promote Their Products to Doctors and Consumers

392. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing 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*. The Marketing Defendants collectively spent more than $14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent

[169] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), at 1.

in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

393. The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.[170] They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[171] Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

**e. The Marketing Defendants Used "Unbranded" Advertising to Promote Opioid Use for Chronic Pain Without FDA Review**

394. The Marketing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the

[170] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al*., *Effects of Patient Medication Requests on Physician Prescribing Behavior: Results of a Factorial Experiment*, 52(2) Med. Care 294-99 (April 2014).
[171] *Id.*

FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

395. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, www.inthefaceofpain.com. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

**f. The Marketing Defendants Funded, Edited And Distributed Publications That Supported Their Misrepresentations**

396. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

397. To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

398. The Marketing Defendants' plans for these materials did not originate in the

departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Marketing Defendants' marketing departments.

399. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

400. The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

401. For example, in 2007 Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[172] published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Lynn Webster, discussed above) stated that the "OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients." The number-one-diagnosed cause of chronic pain in the patients

[172] Donald R. Taylor *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).

studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[173]

### g. The Marketing Defendants Used Detailing to Directly Disseminate Their Misrepresentations to Prescribers

402. The Marketing Defendants' sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors with centrally orchestrated messages. The Marketing Defendants' sales representatives also distributed third-party marketing material to their target audience that was deceptive.

403. Each Marketing Defendant promoted opioids through sales representatives (also called "detailers") and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

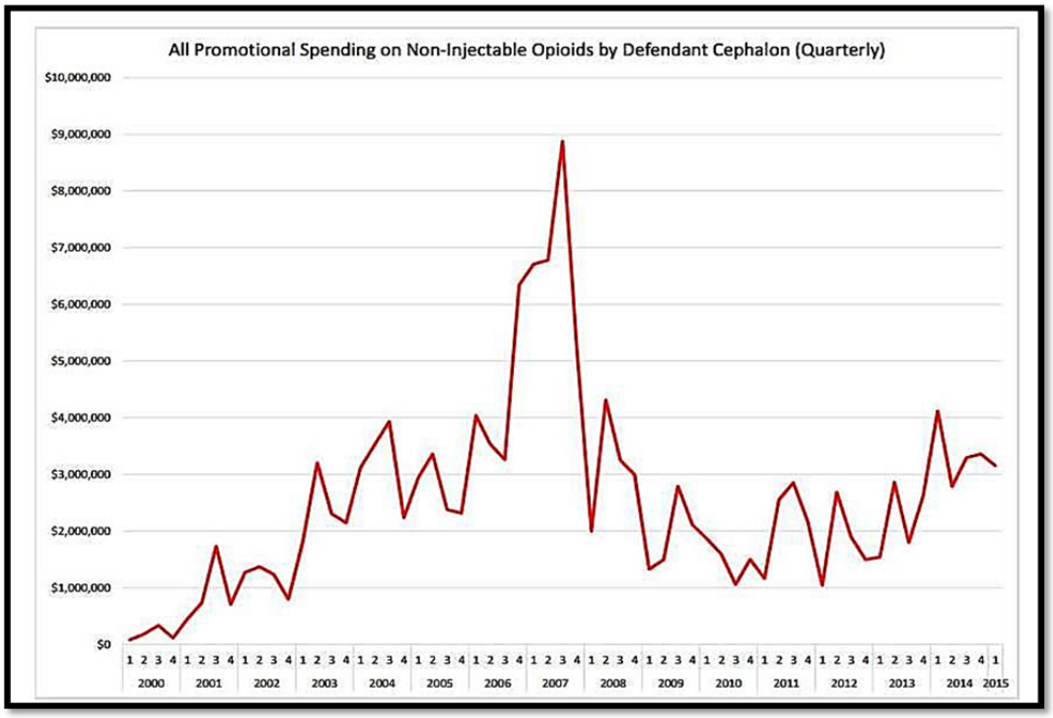
404. In accordance with common industry practice, the Marketing Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and

[173] *Id.* at 287.

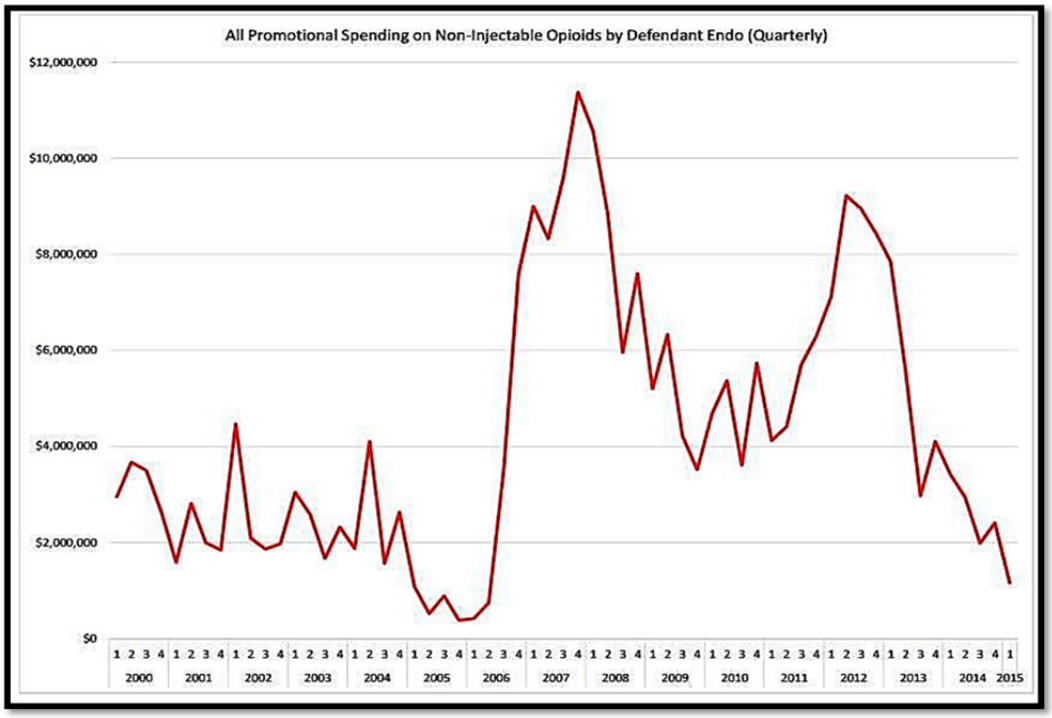
disseminated the misinformation and materials described above.

405. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

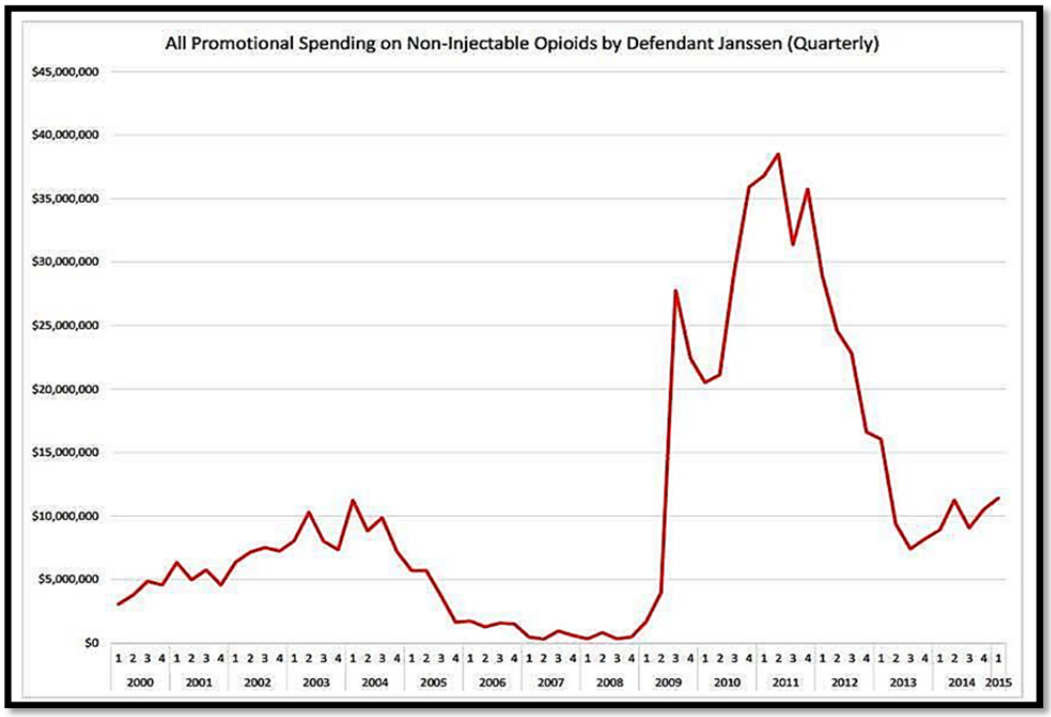
406. Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of more than $27 million in 2007, as shown below:



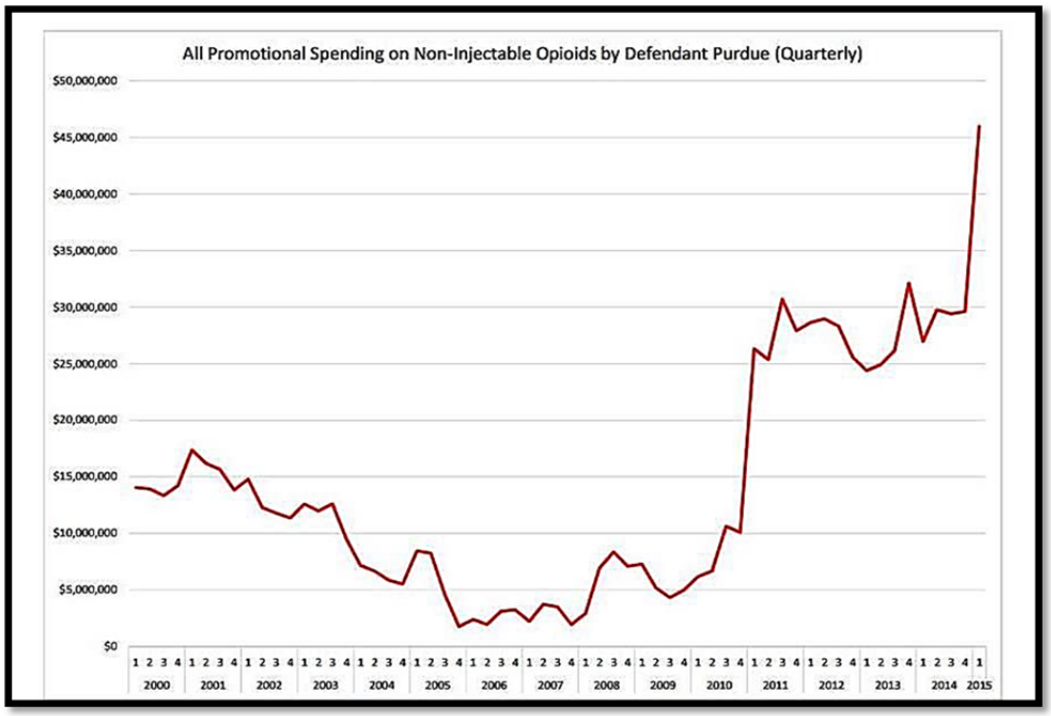
407. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



408. 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:



409. 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 continues to rise, as shown below:




410. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

411. Thousands of prescribers attended Cephalon speaking programs.

**h. Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.**

412. In addition to making sales calls, Marketers' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Marketing Defendants. 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; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Marketing Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

413. As detailed below, Insys paid prescribers for *fake* speakers' programs in exchange for prescribing its product, Subsys. Insys's schemes resulted in countless speakers' programs at which the designated speaker did not speak, and, on many occasions, speaker programs at which the only attendees at the events were the speaker and an Insys sales representative. It was a pay-to-prescribe program.

414. Insys used speakers' programs as a front to pay for prescriptions and paid to push opioids onto patients who did not need them.

### 3. The Marketing Defendants Targeted Vulnerable Populations

415. The Marketing Defendants specifically targeted their marketing at two vulnerable populations—the elderly and veterans.

416. 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 occurs more frequently in elderly patients.

417. The Marketing Defendants promoted the notion—without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. The AGS 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." (emphasis added). As another example, an Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, taught that prescribing opioids to older patients carried "possibly less potential for abuse than in younger patients." Contrary to these assertions, however, 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.

418. Similarly, Endo targeted marketing of Opana ER towards patients over 55 years old. Such documents show Endo treated Medicare Part D patients among the most valuable customer segments.[174] However, in 2013, one pharmaceutical benefits management company recommended against the use of Opana ER for elderly patients and unequivocally concluded: "[f]or patients 65 and older these medications are not safe, so consult your doctor."

419. 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. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to die from an opioid overdose.

420. Yet the Marketing Defendants deliberately targeted veterans with deceptive marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and distributed by APF with grants from Janssen, and Endo, was written as a personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as "underused" and the "gold standard of pain medications" while failing to disclose significant risks of opioid use, including the risks of fatal interactions with

[174] ENDO-CHI_LIT-00050369, at 5,7, and 11; ENDO-CHI_LIT-00076029, at 6.

benzodiazepines. According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from the two drugs together.

421. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001.

#### 4. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys

422. Insys's opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

423. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Cephalon's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them."[175] Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

[175] Press Release, *U.S. Food & Drug Admin., FDA Approves Shared System REMS for TIRF Products* (Dec. 29, 2011).

424. Since its launch, Subsys has been an extremely expensive medication, and its price continues to rise each year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

425. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . . ."[176]

426. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center ("IRC"), to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

427. Subsys has proved to be extremely profitable for Insys. Insys made approximately $330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.

[176] *Fueling an Epidemic*, *supra* note 116.

428. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment of those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

429. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.[177]

430. The Insys "speakers program" was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the

[177] *Id.*

checks."[178] It was a pay-to-prescribe program.

431. Insys's sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

432. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of these doctors to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20 years in prison.

433. In June of 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving $83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at approximately $1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees in exchange for writing prescriptions for Subsys.

434. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things,

[178] Roddy Boyd, *Insys Therapeutics and the New 'Killing It'"*, Southern Investigative Reporting Foundation, The Investigator (April 24, 2015), http://sirf-online.org/2015/04/24/the-new-killing-it/.

misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

435. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received an "honorarium" ranging from $700 to $5,100, and they were allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

436. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys's founder and owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. A U.S. Department of Justice press release explained that, among other things: "Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis."[179] A Drug Enforcement Administration ("DEA") Special Agent in Charge further explained that: "Pharmaceutical

[179] Press Release, U.S. Dep't of Just., U.S. Attorney's Office, Dist. of Mass., Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering (Oct. 26, 2017), https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering.

companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers' health and safety and, indeed, very lives depend on it."[180]

### 5. The Marketing Defendants' Scheme Succeeded, Creating a Public Health Epidemic

#### a. Marketing Defendants Dramatically Expanded Opioid Prescribing and Use

437. The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

438. Endo, for example directed the majority of its marketing budget to sales representatives—with good results: 84% of its prescriptions were from the doctors they detailed. Moreover, as of 2008, cancer and post-operative pain accounted for only 10% of Opana ER's uses; virtually all of Endo's opioid sales—and profits—were from a market that did not exist ten years earlier. Internal emails from Endo staff attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives.

439. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated $15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives

[180] *Id.*

and targeting our marketing efforts to pain specialists."[181] Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.[182] Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[183]

440. Upon information and belief, each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors' prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs. Defendants invested in their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them to continue prescribing opioids or to switch to supposedly "safer" opioids, such as ADF opioids.

441. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.[184] The effects of sales calls on prescribers'

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[181] Cephalon, Inc., Annual Report (Form 10-K), at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.
[182] John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs*, Wall St. J., https://www.wsj.com/articles/SB116252463810112292. (Last Updated Nov. 3, 2006, 12:01 AM).
[183] *Id.*
[184] Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15(2-3) Mktg. Letters 129-145 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *et al*., *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and*

behavior is well documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

442. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[185] These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

443. Thus, both independent studies and Marketing Defendants' own tracking confirm

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*Antipsychotics in Children*, 33(6) Health Affairs 1014-23 (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 221-27 (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).

[185] Catherine S. Hwang, *et al*., *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 (2) JAMA Intern. Med. (Dec. 8, 2014).

that Defendants' marketing scheme dramatically increased their sales.

**b. Marketing Defendants' deception in expanding their market created and fueled the opioid epidemic**

444. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[186] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

445. There is a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[187]

446. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[188] Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[189]

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[186] Theodore J. Cicero *et al*., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16(8) Pharmacoepidemiology and Drug Safety 827-40 (2007).
[187] Robert M. Califf *et al*., *A Proactive Response to Prescription Opioid Abuse*, New Eng. J. Med. 1480-85 (2016), http://www.nejm.org/doi/full/10.1056/NEJMsr1601307.
[188] Rose A. Rudd, *et al*., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2000–2014*, 64 (50 & 51) Ctrs. for Disease Control and Prevention, Morbidity & Mortality Wkly. Rep. 1323-1327 (2016), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.
[189] *Id.*

### E. Defendants Throughout the Supply Chain Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report, and Take Steps to Halt Suspicious Orders

447. The Marketing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

448. For over a decade, as the Marketing Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

449. Defendants are all required to register as either manufacturers or distributors pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74.

450. The Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. The Marketing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more

than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

451. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[190] Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[191]

### 1. All Defendants Have a Duty to Report Suspicious Orders and Not to Ship Those Orders Unless Due Diligence Disproves Their Suspicions

452. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

453. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding Tennessee with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

454. Second, each of the Defendants assumed a duty, when speaking publicly about

[190] Rose A. Rudd *et al.*, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2000–2014*, 64(50 & 51) Ctrs. for Disease Control and Prevention, Morbidity & Mortality Wkly. Rep. 1378-82 (2016), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.
[191] *Id.*

opioids and their efforts to combat diversion, to speak accurately and truthfully.

455. Third, each of the Defendants was required to register with the DEA to manufacture and/or distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. As registrants, Defendants were required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. Defendants were further required to take steps to halt suspicious orders. Defendants violated their obligations under federal law.

456. Fourth, as described below, Defendants also had duties under applicable state laws.

457. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – which includes all manufacturers and distributors of controlled substances—must adhere to the specific security, recordkeeping, monitoring, and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their

obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

458. The CSA requires manufacturers and distributors of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

459. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs." When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class [of each drug] by all manufacturers;

c. Trends in the national rate of disposal of the basic class [of drug];

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class [of drug] and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

460. It is unlawful to manufacture a controlled substance in Schedule II, like

prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

461. To ensure that even drugs produced within quota are not diverted, Federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id*. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id*. Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

462. 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 distributor or manufacturer 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, regardless of whether it deviates from a normal pattern, is enough to trigger the 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 entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

463. In sum, Defendants have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent

diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

464. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together, these laws and industry guidelines make clear that Distributor and Marketing Defendants alike possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

465. Further, these laws and industry guidelines make clear that the Distributor Defendants and Marketing Defendants alike have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

466. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor

Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

467. Marketing Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS Health (now IQVIA). Their extensive boots-on-the-ground presence through their sales forces allows Marketing Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Marketing Defendants regularly mined data, including, upon information and belief, chargeback data, that allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusually high dose prescribing, that would have alerted them, independent of their sales representatives, to suspicious prescribing. These information points gave Marketing Defendants

insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

468. Defendants have a duty, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

469. Defendants breached these duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious overuse of opioids.

### 2. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

470. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

471. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

472. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA." Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

473. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA"), now known as the Healthcare Distribution Alliance ("HDA"), a trade association of pharmaceutical distributors to which Distributor Defendants belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society." Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."

474. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and

customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

475. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." The DEA's September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have 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 same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

476. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, 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 DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

### 3. Defendants Worked Together to Inflate the Quotas of Opioids They Could Distribute

477. Finding it impossible to legally achieve their ever-increasing sales ambitions, Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

478. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Marketing Defendants and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with

manufacturers." Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

479. Distributor Defendants had financial incentives from the Marketing Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

480. The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. *The Washington Post* has described the practice as industry-wide, and the HDA includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt, a prescription opioid manufacturer, acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants," meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

481. The contractual relationships among the Defendants also include vault security

programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. The manufacturers negotiated agreements whereby the Marketing Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

482. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

483. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

484. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[192] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[193]

485. The Defendants who stood to profit from expanded prescription opioid use are

[192] Matthew Perrone & Ben Wieder , *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, The Ctr. for Pub. Integrity, https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic. (Last Updated Dec. 15, 2016, 9:09 AM) (emphasis added).
[193] *Id*.

members of and/or participants in the PCF.[194] In 2012, membership and participating organizations included Endo, Purdue, Actavis, and Cephalon. Each of the Marketing Defendants worked together through the PCF. But, the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[195] The Distributor Defendants participated directly in the PCF as well.

486. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants including Actavis, Endo, Purdue, Mallinckrodt, and Cephalon were members of the HDA. Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants by advocating for the many benefits of members, including "strengthen[ing] . . . alliances."[196]

487. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale

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[194] *PAIN CARE FORUM 2012 Meetings Schedule*, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

[195] *Id*.; The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *Executive Committee*, Healthcare Distribution Alliance https://www.healthcaredistribution.org/about/executive-committee (last accessed Apr. 25, 2018).

[196] *Manufacturer Membership*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en. (last accessed Apr. 25, 2018).

distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[197] Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Marketing and Distributor Defendants.

488. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other's businesses.[198] For example, the manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

489. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Cardinal Health, and McKesson and their subsidiaries.

490. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

491. The HDA also offers a multitude of conferences, including annual business and

[197] *Id.*
[198] *Manufacturer Membership Application*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[199] The conferences also gave the Marketing and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[200] The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. It is clear that the Marketing Defendants embraced this opportunity by attending and sponsoring these events.[201]

492. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation

[199] *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, https://web.archive.org/web/20150424054305/https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.
[200] *Id.*
[201] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://web.archive.org/web/20160119143358/https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

in this committee includes distributor and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

493. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[202] For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers . . . ." The Marketing Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

494. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to

[202] *Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set*, Healthcare Distribution Alliance (Apr. 27, 2011), (, https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

engage in the unlawful sale of prescription opioids.

495. The HDA and the PCF are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

496. Publications and guidelines issued by the HDA nevertheless confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an *amicus* brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

497. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

498. The Defendants' scheme had a decision-making structure driven by the Marketing Defendants and corroborated by the Distributor Defendants. The Marketing Defendants worked together to control the state and federal government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal

to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

499. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

500. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

501. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

502. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

503. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

#### 4. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers

504. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. The data

necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

505. Publicly available information confirms that Distributor and Marketing Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

506. This information includes the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described in paragraphs 186 and 200;

d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

507. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

508. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

509. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[203] The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

510. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data

[203] *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enf't Admin. Diversion Control Div., https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., & Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC (Oct. 2010), https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.[204]

511. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[205]

512. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[206]

513. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.[207]

514. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

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[204] A Verispan representative testified that the Distributor Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 661712, *9-10 (Feb. 22, 2011).

[205] Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How We Turned a Mountain of Data into a Few Information-Rich Molehills*, (accessed on February 15, 2018), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf, Figure 2 at p.3.

[206] Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, *467-471 (Feb. 22, 2011).

[207] In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vendor, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." Joint Appendix in *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

515. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against distributors in 178 registrant actions between 2008 and 2012[208] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders, all for failure to report suspicious orders.[209]

516. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

517. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's

[208] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.
[209] *Id.*

diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.[210] In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[211]

518. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[212] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[213] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

519. A Kadian prescriber guide discusses abuse potential of Kadian. It is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the

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[210] Meier, *supra* note 18, at 298-300.
[211] *Id*.
[212] Harriet Ryan *et al*., *More Than 1 million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, Los Angeles Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.
[213] *Id*.

following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state."[214] The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.[215]

520. Defendant' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

521. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

522. For example, at a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers: "To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into 'the big leak'. We need to fill the bucket faster than it leaks." "The selling message should reflect the

[214] ACTAVIS0947868-72, at 68-69.
[215] *Id.*, at 72.

opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow/ Grow = New Patient Starts and Conversions."[216] In an example of how new patients + a high volume physician can impact performance: "102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week."[217]

523. The same is true for other Defendants.

524. This focus on marketing to the highest prescribers demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

525. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Marketing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[218]

526. But given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted

[216] ACTAVIS0969604-27, at 616.
[217] *Id.*, at 625.
[218] Meier, *supra* note 18, *at* 179.

authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

527. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

528. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

### 5. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

529. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids following into communities across America. Despite the notice described above, and in disregard of their duties, Defendants continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders.

530. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

531. For example, on January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for, *inter alia*, 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; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."

532. McKesson further admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers" including the McKesson Distribution Center located in Washington Court House, Ohio. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which (including the one in Washington Courthouse, Ohio), investigators found "were supplying pharmacies that sold to criminal drug rings."

533. Similarly, in 2017, the Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and]

Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."

534. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";

b. "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and

c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

535. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to

show that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal Health settled for $20 million.

536. Thus, it is the various governmental agencies who have alleged or found—and the Defendants themselves who have admitted—that the Defendants, acting in disregard of their duties, pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

### 6. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

537. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

538. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in

2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

539. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

540. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

541. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

542. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, HDMA and the National Association of Chain Drugstores ("NACDS"), filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[219]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

543. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

544. Defendant Mallinckrodt similarly claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that

[219] Brief for HDMA and NACDS, *Masters Pharms., Inc. v. U.S. Drug Enf't Admin.*, Case No. 15-1335, 2016 WL 1321983 (D.C. Cir. April 4, 2016), at *3-4, *25.

includes educational efforts, monitoring for suspicious orders of controlled substances . . . ."

545. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[220]

546. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

547. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[221] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[222] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and

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[220] *Setting The Record Straight On OxyContin's FDA-Approved Label*, Purdue Pharma (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; *Setting The Record Straight On Our Anti-Diversion Programs*, Purdue Pharma (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[221] *Opioids With Abuse-Deterrent Properties*, Purdue Pharma, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.

[222] *Opioids & Corporate Responsibility*, Purdue Pharma, http://www.purduepharma.com/about/company-values/opioids-corporate-responsibility/.

enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[223]

548. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

549. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

**F. <u>The Opioid Epidemic in Cannon County</u>**

550. Cannon County is at the center of a rising opioid epidemic in Tennessee.

551. According to the Centers for Disease Controls, in recent years, the number of opioid prescriptions in Cannon County has consistently exceeded 1 prescription for each man, woman, and child in Cannon County, inflating at times to almost 1.3 prescriptions for each person in Cannon County. The opioid prescription rate in Cannon County has been at times in

[223] *Setting The Record Straight On Our Anti-Diversion Programs*, Purdue Pharma (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

recent years more than 80% higher than the national average.

552. Cannon County funds emergency and ambulance services for its residents and has seen a substantial increase in the amount of emergency services needed due to opioid-related events.

553. Cannon County has been forced to spend substantial amounts of money on "Narcan" and other medication designed to treat opioid overdoses and abuse in the County for its emergency services and other programs.

554. The county has increased expenditures on juvenile and probation services and court matters due to the rising opioid epidemic.

555. Cannon County has suffered by being required to spend increasing amounts of money and resources to combat the increasing opioid epidemic over the past decade.

556. Cannon County has expended its taxpayers' resources to deal with each of the aforementioned situations caused by the opioid epidemic, as well as many others.

557. Cannon County lacks resources it needs to address the opioid epidemic plaguing its county.

### G. The Defendants Conspired to Engage in the Wrongful Conduct Complained of Herein and Intended to Benefit Both Independently and Jointly from Their Conspiracy

#### 1. Conspiracy Among Marketing Defendants

558. The Marketing Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

559. This interconnected and interrelated network relied on the Marketing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants intended to mislead consumers and medical providers of the appropriate uses, risks, and safety of opioids.

560. The Marketing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

561. The Marketing Defendants knew that none of these propositions is true and that there was no evidence to support them.

562. Each Marketing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, health care providers, and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

563. What is particularly remarkable about the Marketing Defendants' effort is the seamless method in which the Marketing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers of the safety of opioids, and to hide their

actual risks and dangers. In doing so, the Marketing Defendants effectively built a new – and extremely lucrative opioid marketplace for their select group of industry players.

564. The Marketing Defendants' unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

565. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants.

566. The most unnerving tactic utilized by the Marketing Defendants' network, was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective unbiased and disinterested experts in the field, scientific method, and an unfounded theory or proposition would, or should, never gain traction.

567. Marketing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Marketing Defendants were able to create a false consensus through their materials and references.

568. An illustrative example of the Marketing Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These

patients were ***not*** given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

569. Nonetheless, Marketing Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids in connection with taking opioids despite its obvious shortcomings. Marketing Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

570. Marketing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers that opioids were not a concern. The enormous impact of Marketing Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particularly, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy…

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

### 2. Conspiracy Among All Defendants

571. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective

advantage. Defendants agreed among themselves to increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

572. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

573. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below and in section V below, including, for example, membership in the Healthcare Distribution Alliance ("HDA").

574. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

575. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the

reporting or suspicious orders to ensure consistency in their dealings with DEA.

576. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had not basis for refusing to increase or decrease production quotas due to diversion.

577. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

## H. Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations As Defenses

### 1. Continuing Conduct.

578. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

579. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

### 2. Equitable Estoppel and Fraudulent Concealment

580. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state

and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, the Plaintiff, and Plaintiff's Community, that they are working to curb the opioid epidemic.

581. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

582. As set forth herein, the Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Marketing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Marketing Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

583. Defendants also concealed from Plaintiff the existence of Plaintiff's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the

public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiff, and deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

584. Plaintiff did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on Plaintiff, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

585. The Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in Tennessee and in Plaintiff's Community deceived the medical community, consumers, Tennessee, and Plaintiff's Community.

586. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities. On April 11, 2018, the Northern District of Ohio Ordered the transactional ARCOS data be produced, over Defendants' strenuous objections.

587. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's Community. Plaintiff and Plaintiff's Community did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

588. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law

and consent orders.

## I. Facts Pertaining to Punitive Damages

589. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

590. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this knowledge, took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

591. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities and government liabilities across the country.

592. Defendants' actions demonstrated both malice and also aggravated and egregious

fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Marketing Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

### 1. The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

593. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings, and prosecutions. These governmental and regulatory actions included:

#### a. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic

594. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." The March 30, 2000 letter detailed numerous ways in which Janssen's marketing was misleading.

595. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The September 2, 2004 letter detailed a series of unsubstantiated, false, or misleading claims.

596. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

**b. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Uses**

597. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses.

598. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

**c. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora**

599. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned:

"Fentora should not be used to treat any type of short-term pain." Indeed, FDA specifically denied Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

600. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

601. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

**d. <u>A Guilty Plea and a Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin</u>**

602. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate,

misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

603. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly $900 million dollars on lobbying and political contributions— eight times what the gun lobby spent during that period.

### 2. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

604. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

605. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply,

people die. That's just it. People die." He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

606. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."

607. Government actions against the Defendants with respect to their obligations to control the supply chain and prevent diversion include:

a. 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 that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. 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, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

h. 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 Facility.

608. McKesson's deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 McKesson 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."

609. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite its awareness of the great probability that its failure to do so would cause

substantial harm.

610. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million 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; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson's 2017 agreement with DEA documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

611. As *The Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the $150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

612. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

> DAVID SCHILLER: If they would stayed in compliance with their authority and held those that they're supplying the pills to, the

> epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> [INTERVIEWER:] And they had none.
>
> DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[224]

613. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";

b. "[d]ocumentation evidencing new customer due diligence was incomplete";

c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and

d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

[224] Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/.

614. Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

615. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in *The Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings." "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."

616. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were

detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

617. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the *Los Angeles Times* that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

618. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

619. The New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and yet that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

620. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing

of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

621. As all of the governmental actions against the Marketing Defendants and against all the Defendants shows, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

## IV. FACTS PERTAINING TO CLAIMS UNDER RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ("RICO") ACT

### A. The Opioid Marketing Enterprise

#### 1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

622. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants[225] formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

623. In order to unlawfully increase the demand for opioids, the RICO Marketing Defendants formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The RICO Marketing

[225] The RICO Marketing Defendants referred to in this section are those named in the First Claim for Relief under 28 U.S.C. § 1964(c), including Purdue, Cephalon, Janssen, Endo and Mallinckrodt.

Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.[226]

624. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the RICO Marketing Defendants named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

625. The scheme devised, implemented and conducted by the RICO Marketing Defendants was a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' drugs. The RICO Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

626. There was regular communication between the RICO Marketing Defendants,

[226] *Fueling an Epidemic*, *supra* note 116.

Front Groups and KOLs, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the RICO Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

627. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

628. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing

Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

629. As public scrutiny and media coverage focused on how opioids ravaged communities in Tennessee and throughout the United States, the Front Groups and KOLS did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

630. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC Guideline; and (4) efforts to limit prescriber accountability.

631. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC Guideline. Members of the Opioid Marketing Enterprise criticized or

undermined the CDC Guideline which represented "an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."

632. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

633. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."

634. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

635. The impact of the Opioid Marketing Enterprise's scheme is still in place—*i.e.*, the opioids continue to be prescribed and used for chronic pain throughout the area of Cannon County, and the epidemic continues to injure Plaintiff, and consume the resources of Plaintiff's health care and law enforcement systems.

636. As a result, it is clear that the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing 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.

### 2. The Conduct of the Opioid Marketing Enterprise violated Civil RICO

637. From approximately the late 1990s to the present, each of the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the RICO Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically

over meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

638. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the RICO Marketing Defendants and corroborated by the KOLs and Front Groups. The RICO Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that

representations made by KOLs, Front Groups, and the RICO Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States and Tennessee. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on the Marketing Defendants for their financial structure and for career development and promotion opportunities.

639. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

640. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their

industry sponsors."[227] "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[228]

641. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the RICO Marketing Defendants.

642. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

[227] *Id.* at 2.
[228] *Id.*

### 3. The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

643. As discussed in detail above, the RICO Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, and AGS. The Front Groups, which appeared to be independent, but were not, transmitted the RICO Marketing Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

644. The RICO Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

645. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

### 4. Pattern of Racketeering Activity

646. The RICO Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

647. The pattern of racketeering activity used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute

and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the RICO Marketing Defendants' misrepresentations.

648. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud Cannon County consumers, the Plaintiff, and other intended victims.

649. The RICO Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

650. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain, to, prescribers, regulators and the public, including Plaintiff, the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

651. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire

facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and Plaintiff's Community;

b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally

d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the Plaintiff's Community that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

652. In addition to the above-referenced predicate acts, it was intended by and

foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

653. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and the Plaintiff: (a) the fraudulent nature of the RICO Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

654. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

655. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines

656. The RICO Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while

simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

### B. The Opioid Supply Chain Enterprise

657. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent."[229] Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the "RICO Supply Chain Defendants" (Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

658. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act ("CSA"). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. The CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system

[229] McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response (last visited, Apr. 21, 2018).

cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

659. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[230] Critically, these Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

660. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets. The RICO Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

661. The RICO Supply Chain Defendants' scheme required the participation of all. If

[230] 21 C.F.R. 1301.74(b).

any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the RICO Supply Chain Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance -- intentionally remaining silent to ensure the largest possible financial return.

662. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Supply Chain Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and

report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

663. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

664. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. the quotas for prescription opioids should be increased;

b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

e. they did not have the capability to identify suspicious orders of controlled substances.

665. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[231]

[231] *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/. (Last U updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The*

666. The CSA and the Code of Federal Regulations, require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

667. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

668. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the

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*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; Lenny Bernstein & 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; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

diversion of opioids into the illicit market.

669. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

670. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

671. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d. RICO Supply Chain Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of the

RICO Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Marketing Defendants;

k. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;

l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

672. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

| **Defendant Group Name** | **Company Names** | **Drugs** | | |
|---|---|---|---|---|
| | | **Drug Name** | **Chemical Name** | **CSA Schedule** |
| **Purdue** | (1) Purdue Pharma, LP,<br>(2) Purdue Pharma, Inc.,<br>(3) The Purdue Frederick Company | OxyContin | Oxycodone hydrochloride extended release | Schedule II |
| | | MS Contin | Morphine sulfate extended release | Schedule II |
| | | Dilaudid | Hydromorphone hydrochloride | Schedule II |
| | | Dilaudid-HP | Hydromorphone hydrochloride | Schedule II |
| | | Butrans | Buprenorphine | Schedule II |
| | | Hysinga ER | Hydrocodone bitrate | Schedule II |
| | | Targiniq ER | Oxycodone hydrochloride | Schedule II |

| Defendant Group Name | Company Names | Drugs | | |
|---|---|---|---|---|
| | | **Drug Name** | **Chemical Name** | **CSA Schedule** |
| **Cephalon** | (1) Cephalon, Inc.,<br>(2) Teva Pharmaceutical Industries, Ltd.,<br>(3) Teva Pharmaceuticals USA, Inc. | Actiq | Fentanyl citrate | Schedule II |
| | | Fentora | Fentanyl citrate | Schedule II |
| | | Generic OxyContin | Oxycodone hydrochloride | Schedule II |
| **Endo** | (1) Endo Health Solutions, Inc.,<br>(2) Endo Pharmaceuticals Inc.,<br>(3) Qualitest Pharmaceuticals, Inc. (*wholly-owned subsidiary of Endo*) | Opana ER | Oxymorphone hydrochloride extended release | Schedule II |
| | | Opana | Oxymorphone hydrochloride | Schedule II |
| | | Percodan | Oxymorphone hydrochloride and aspirin | Schedule II |
| | | Percocet | Oxymorphone hydrochloride and acetaminophen | Schedule II |
| | | Generic oxycodone | | Schedule II |
| | | Generic oxymorphone | | Schedule II |
| | | Generic hydromorphone | | Schedule II |
| | | Generic hydrocodone | | Schedule II |
| **Mallinckrodt** | (1) Mallinckrodt plc,<br>(2) Mallinckrodt LLC (*wholly-owned subsidiary of Mallinckrodt plc*) | Exalgo | Hydromorphone hydrochloride | Schedule II |
| | | Roxicodone | Oxycodone hydrochloride | Schedule II |
| **Actavis** | (1) Allergan plc,<br>(2) Actavis LLC,<br>(3) Actavis Pharma, Inc.,<br>(4) Actavis plc,<br>(5) Actavis, Inc.,<br>(6) Watson Pharmaceuticals, Inc.,<br>(7) Watson Pharma, Inc. | Kadian | Morphine Sulfate | Schedule II |
| | | Norco (Generic of Kadian) | Hydrocodone and acetaminophen | Schedule II |
| | | Generic Duragesic | Fentanyl | Schedule II |
| | | Generic Opana | Oxymorphone hydrochloride | Schedule II |

673. Each of the RICO Supply Chain Defendants, identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

674. The RICO Supply Chain Defendants used the internet and other electronic

facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

675. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

676. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

677. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

678. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiff that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could

profit.

679. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

680. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as Defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

681. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

682. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

683. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.[232]

684. 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, Plaintiff's Community and the Plaintiff. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The RICO Supply Chain Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

685. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

686. Sales representatives marketed OxyContin, including in Cannon and surrounding areas, as a product "to start with and to stay with," and Purdue deliberately exploited a

[232] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

misconception it knew many doctors held that oxycodone was less potent than morphine.[233] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. *The New Yorker* reported that "[i]n 2002, a sales manager from the company, William Gergely, told a state investigator in Florida that Purdue executives 'told us to say things like it is "virtually" non-addicting.'"[234]

687. Purdue caused the publication and distribution of false and deceptive guidelines on opioid prescribing. For example, as set forth above, Purdue paid $100,000 to the Federation of State Medical Boards "FSMB" to help print and distribute its guidelines on the use of opioids to treat chronic pain to ***700,000*** practicing doctors.

### C. Effect of Opioid Marketing Enterprise and Opioid Supply Chain Enterprise on Cannon County

688. As described herein, Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from consumers, based on their misrepresentations and omissions. The predicate acts also had the same or similar results, participants, victims and methods of commission. The predicate acts were related and not isolated events. The predicate acts all had the purpose of generating significant revenue and profits for Defendants, at the expense of Cannon County. The predicate acts were committed or caused to be committed by Defendants through their participation in the enterprise and in furtherance of their fraudulent scheme and were interrelated in that they involved obtaining Cannon County's and its residents' funds.

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[233] Keefe, *Empire of Pain, supra* note 38.
[234] *Id*.

689. As fully alleged herein, Cannon County, along with scores of other counties and municipalities, relied upon representations and omissions that were made or caused by Defendants. Plaintiff's reliance is evidenced by the fact that they purchased opioids, which never should have been introduced into the U.S. stream of commerce, and the use of which has now caused a nationwide epidemic of addiction and overdose.

690. Cannon County's injuries, and those of other consumers, were proximately caused by Defendants' racketeering activity, which directly caused the over-prescription, over-purchase, and over-consumption of opioids. But for Defendants' misstatements and omissions and the scheme employed by the Opioid Marketing Enterprise and the Opioid Supply Chain Enterprise, Cannon County and its residents would not have paid for opioid prescriptions for chronic pain and would not be bearing the costs of its current opioid epidemic.

691. By reason of, and as a result of the conduct of each of the Defendants, and in particular, their pattern of racketeering activity, Cannon County has been injured in its business and property in multiple ways, including, but not limited to, suffering increased law enforcement and public works expenditures, judicial proceedings, and prisons, increased expenditures for overtime, mental health treatment and workers' compensation for its employees, increased emergency and treatment services and autopsies, damage to emergency equipment and vehicles, the processing and payment of fraudulent prescriptions, and lost productivity, economic opportunity and tax revenue.

692. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and proximately caused injuries and damages to Cannon County, and Cannon County is entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

## CLAIMS FOR RELIEF

## FIRST CLAIM FOR RELIEF

**Violation of RICO, 18 U.S.C. § 1961 *et seq*. – Opioid Marketing Enterprise (Against Defendants Purdue, Cephalon, Janssen, Endo, and Mallinckrodt (the "RICO Marketing Defendants"))**

693. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

694. The RICO Marketing Defendants through the use of "Front Groups" that appeared to be independent of the RICO Marketing Defendants; through the dissemination of publications that supported the RICO Marketing Defendants' scheme; through continuing medical education ("CME") programs controlled and/or funded by the RICO Marketing Defendants; by the hiring and deployment of so-called "key opinion leaders," ("KOLs") who were paid by the RICO Marketing Defendants to promote their message; and through the "detailing" activities of the RICO Marketing Defendants' sales forces conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, *i.e.*, to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine false propositions alleged earlier were true. In so doing, each of the RICO Marketing Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

695. The Opioid Marketing Enterprise alleged above is an association-in-fact enterprise that consists of the RICO Marketing Defendants (Purdue Cephalon, Janssen, Endo, and Mallinckrodt); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

696. Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids.

697. Specifically, the RICO Marketing Defendants each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

698. Each of the Front Groups helped disguise the role of RICO Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Defendants false

messages.

699. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants to influence their peers' medical practice by promoting the Marketing Defendants' false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Defendants' role in the enterprise and the enterprise's existence.

700. Further, each of the RICO Marketing Defendants, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the RICO Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

701. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal

entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO Marketing Defendants and each of the Front Groups and KOLs; and (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

702. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

703. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

704. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

705. The RICO Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

706. Indeed, as summarized herein, the RICO Marketing Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

707. Because the RICO Marketing Defendants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiff has described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to Tennessee consumers, prescribers, regulators and Plaintiff, and how those acts were in furtherance of the scheme.

708. 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 Tennessee consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

709. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

710. 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.

711. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Tennessee consumers, prescribers, regulators and the Plaintiff. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Tennessee consumers, prescribers, regulators and the Plaintiff. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid

Marketing Enterprise.

712. Each of the RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

713. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

714. 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. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

715. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiff's injuries, as described below, were not unexpected, unforeseen or independent.[235] Rather, as Plaintiff alleges, the RICO Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were

[235] *Travelers Prop. Cas. Co. of Am. v. Actavis, Inc.*, 16 Cal. App. 5th 1026, 1030 (2017)

highly addictive and subject to abuse.[236] Nevertheless, the RICO Marketing Defendants engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

716. It was foreseeable and expected that the RICO Marketing Defendants creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.[237]

717. Specifically, the RICO Marketing Defendants' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters,

[236] *Id*. at 1041
[237] *Id*.

and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's community;

l. Costs associated with extensive clean-up of public parks, spaces, and facilities of needles and other debris and detritus of opioid addiction;

m. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

n. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

718. Plaintiff's injuries were directly and thus proximately caused by these Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic the RICO Marketing Defendants created through their Opioid Marketing Enterprise, Plaintiff would not have lost money or property.

719. Plaintiff is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

720. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*:

a. Actual damages and treble damages, including pre-suit and post-judgment interest;

b. An order enjoining any further violations of RICO;

c. An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;

d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;

e. An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use, except as specifically approved by the FDA;

f. An order enjoining any future marketing of opioids through non-branded marketing including through the Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;

g. An order enjoining any future marketing to vulnerable populations, including but not limited to, persons over the age of fifty-five, anyone under the age of twenty-one, and veterans;

h. An order compelling the Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court, but not less than print advertisements in national and regional newspapers and medical journals, televised broadcast on major television networks, and displayed on their websites, concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) pseudoaddiction is really addiction, not a sign of undertreated addiction; (4) withdrawal from

opioids is not easily managed; (5) increasing opioid dosing presents significant risks, including addiction and overdose; (6) long term use of opioids has no demonstrated improvement of unction; (8) use of time-released opioids does not prevent addiction; (9) abuse-deterrent formulations do not prevent opioid abuse; and (10) that manufacturers and distributors have duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and diversion but failed to do so;

i. An order enjoining any future lobbying or legislative efforts regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

j. An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;

k. An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

l. An order establishing a National Foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the Defendants in an amount to be determined by the Court;

m. An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious orders or diversion of opioids;

n. An order requiring all Defendants to publicly disclose all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding suspicious orders for or the diversion of opioids;

o. An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Marketing and Supply Chain Enterprises, including any interest in property associated with the Marketing and Supply Chain Enterprises;

p. Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Marketing and Supply Chain Enterprises identified in this Complaint, as the Court sees fit;

q. Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;

r. Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association or enterprise named in the Complaint regarding the manufacture or distribution of opioids;

s. Forfeiture as deemed appropriate by the Court; and

721. Attorney's fees and all costs and expenses of suit.

## SECOND CLAIM FOR RELIEF

**Violation of RICO, 18 U.S.C. § 1961 *et seq*. – Opioid Supply Chain Enterprise (Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen – (the "RICO Supply Chain Defendants"))**

722. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

723. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

724. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

725. The RICO Supply Chain Defendants were of members the Healthcare Distribution Alliance (the "HDA").[238] Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA

[238] *History,* Health Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history. (last accessed on September 15, 2017).

to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

726. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

727. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

728. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made

possible by the RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

729. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

730. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

731. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

732. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C.

§ 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

c. Controlled Substance Violations: The RICO Supply Chain Defendants who are Distributor Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

733. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

734. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

735. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

736. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

737. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants

had to agree to implement similar tactics regarding manufacturing and distribution of prescription opioids and refusing to report suspicious orders.

738. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

739. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

740. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants are distinct from the enterprise.

741. 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.

742. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

743. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

744. It was foreseeable to the RICO Supply Chain Defendants that Plaintiff would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

745. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

746. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. Plaintiff was injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

747. The RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.[239] Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they

[239] *Travelers Prop. Cas. Co. of Am. V. Actavis, Inc.*, 16 Cal. App. 5th 1026, 1030 (2017)

knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.[240]

748. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

749. Specifically, Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;

[240] *City of Everett v. Purdue Pharma L.P.*, Case No. 17-cv-00209, 2017 WL 4236062, *2 (W.D. Wash. Sept. 25, 2017).

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's community;

l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

750. Plaintiff's injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by Defendants' conduct, Plaintiff would not have lost money or property.

751. Plaintiff's injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

752. Plaintiff is the most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

753. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the

Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, and all of the relief sought into the First Claim for Relief, as the Court deems just and applicable.

## THIRD CLAIM FOR RELIEF

### COMMON LAW PUBLIC NUISANCE
### (Tennessee Common Law)

754. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

755. Under Tennessee common law, a "public nuisance" is defined as any "condition of things which is prejudicial to health, comfort, safety, property, sense of decency or morals of the citizens at large, resulting either from an act not warranted by law, or from neglect of a duty imposed by law." *State ex. rel. Swann v. Pack*, 527 S.W.2d 99, 113 (Tenn. 1975).

756. A common law nuisance "extends to everything that endangers life or health, gives offense to the senses, violates the laws of decency, or obstructs the reasonable or comfortable use of property." *Id.*

757. The public nuisance complained of herein includes the over-saturation, unlawful availability, and abuse of opioids in Cannon County for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

758. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to Cannon County and its residents.

759. The nuisance includes the over-saturation, unlawful availability, and abuse of opioids as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

760. The Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

761. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Cannon County.

762. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management.

763. Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs.

764. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community, including places such as Cannon County, would suffer as a result.

765. The Defendants' actions were a substantial factor in opioids becoming widely available and widely used. Without the Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted, including in Cannon County.

766. Defendants' nuisance-causing activities include selling, and/or facilitating the illegal sale of, prescription opioids from premises in and around Cannon County to unintended users in the community, including people at risk of overdose and criminals.

767. The Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of prescription opioids, and their failure to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

768. The Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies

and into the black market, including so-called "pill mills" and other dealers.

769. The Defendants also enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including through alleged "pill mills" as well as other drug dealers, with actual knowledge, intent, and/or reckless or negligent disregard that such opioids would be illegally trafficked and abused.

770. The public nuisance created by Defendants endangers the health and safety of the Cannon County and its residents.

771. The public nuisance created by Defendants has caused, and continues to cause, significant harm to, and the expenditure of taxpayer dollars by, Cannon County including, but not limited to the following:

a. The staggering rates of opioid use among adults in Cannon County has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths. It has also resulted in increased crime and property damage in Cannon County.

b. Infants have been born addicted to opioids due to pre-natal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. The Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for illicit use and fueled a new wave of addiction, abuse, and injury. The Defendants' scheme created a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.

d. The diversion of opioids into the secondary, illicit market and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of Cannon County.

e. Adults and children in Cannon County who have never taken opioids have also suffered the costs of the Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids. All these problems

harm Cannon County by diminishing Cannon County's revenues and forcing it to make increased expenditures.

772. Cannon County public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resource which could be used to benefit the public at large in Cannon County.

773. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in the Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Defendants' dissemination of false "scientific" facts and advice.

774. At all times, the Defendants possessed the right and ability to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale into the surrounding Cannon County. The Defendants had the power to shut off the supply of illicit opioids into the County. The Defendants had the power to stop providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products

775. As a direct and proximate result of the public nuisance, Cannon County has sustained harm by spending a substantial amount of money trying to fix the societal harms caused by the Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, healthcare, child services, judicial services, incarceration, medical examinations, burials, and law enforcement.

776. Defendants should be required to pay the expenses the Cannon County has incurred or will incur in the future to fully abate the nuisance.

## FOURTH CLAIM FOR RELIEF

### STATUTORY PUBLIC NUISANCE
### (Tenn. Code Ann. § 29-3-101, *et seq.)*

777. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

778. Under Tennessee statutory law, "[a]ny person who uses, occupies, establishes or conducts a nuisance, or aids or abets therein, and the owner, agent or lessee of any interest in any such nuisance, together with the persons employed in or in control of any such nuisance by any such owner, agent or lessee, is guilty of maintaining a nuisance and such nuisance shall be abated as provided hereinafter." Tenn. Code Ann. § 29-3-101 (b).

779. The term "nuisance" includes "[a]ny place in or upon which. . . [the] unlawful sale of any regulated legend chug, narcotic or other controlled substance . . . are carried on or permitted, and personal property, contents, furniture, fixtures, equipment and stock used in or in connection with the conducting and maintaining any such place for any such purposes." *Id.* § 29-3-101 (a)(2)(A).

780. The nuisance statute further provides that, in an "order of abatement, the court may . . . assess costs of public services required to abate or manage the nuisance, including, but not limited to, law enforcement costs, if any, caused by the public nuisance." *Id.* § 29-3-110.

781. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to Cannon County and their residents.

782. The public nuisance complained of herein includes the over-saturation, unlawful availability, and abuse of opioids in Cannon County for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

783. The Defendants knew or should have known that their promotion of opioid use

would create a public nuisance:

a. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Cannon County.

b. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management.

c. Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs.

d. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

784. The Defendants' actions were a substantial factor in opioids becoming widely available and widely used. Without the Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

785. Defendants' nuisance-causing activities include selling, and/or facilitating the illegal sale of, prescription opioids from premises in and around Cannon County to unintended users in Cannon County, including people at risk of overdose and criminals.

786. The Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of prescription opioids, and their failure to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

787. The Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including so-called "pill mills" and other dealers.

788. The Defendants also enabled and/or failed to prevent the illegal diversion of

prescription opioids into the black market, including "pill mills" and other drug dealers, with actual knowledge, intent, and/or reckless or negligent disregard that such opioids would be illegally trafficked and abused.

789. The public nuisance created by Defendants endangers the health and safety of Cannon County and its residents.

790. The public nuisance created by Defendants has caused, and continues to cause, significant harm and taxpayer dollars to Cannon County including, but not limited to the following:

a. The staggering rates of opioid use among adults in Cannon County has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths. It has also resulted in increased crime and property damage in Cannon County.

b. Infants have been born addicted to opioids due to pre-natal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. The Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. The Defendants' scheme created a new secondary market for opioids - providing both the supply of narcotics to sell and the demand of addicts to buy them.

d. The diversion of opioids into the secondary, illicit market and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of Cannon County.

e. Adults and children in Cannon County who have never taken opioids have also suffered the costs of the Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids. All these problems harm Cannon County by leading to decreased revenues for Cannon County and increased expenditures.

791. Public resources are being unreasonably consumed in efforts to address the opioid

epidemic, thereby eliminating available resource which could be used to benefit the public at large in Cannon County. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in the Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Defendants' dissemination of false "scientific" facts and advice. Moreover, there is no legitimate societal interest to the diversion and/or illegal sale of prescription opioids.

792. At all times, the Defendants possessed the right and ability to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale into the surrounding Cannon County. The Defendants had the power to shut off the supply of illicit opioids into Cannon County. The Defendants had the power to stop providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products.

793. As a direct and proximate result of the public nuisance, Cannon County has sustained harms by spending a substantial amount of money trying to fix the societal harms caused by the Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, healthcare, child services, and law enforcement.

794. Defendants should be required to pay the expenses Cannon County has incurred or will incur in the future to fully abate the nuisance.

## FIFTH CLAIM FOR RELIEF

### Negligence Against the Marketing Defendants

795. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

796. Negligence *per se* is established where the defendant violates a statutory duty and where the statute is intended to protect against the result of the violation, the plaintiff is within the class intended to be protected by the statute, and the statutory violation is a proximate cause of the plaintiff's injury.

797. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty and the plaintiff sustained an injury or loss proximately caused by the defendant's breach

798. To prevail on a negligence claim, a plaintiff must establish (1) a duty of care owed by the defendant to the plaintiff; (2) conduct by the defendant falling below the standard of care amounting to a breach of that duty; (3) an injury or loss; (4) causation in fact; and (5) proximate or legal cause. *Naifeh v. Valley Forge Life Ins. Co.*, 204 S.W.3d 758, 771 (Tenn. 2006).

799. Each Defendant had an obligation and duty to exercise reasonable care in the manufacturing, marketing and distribution of highly dangerous opioid drugs in and around Cannon County.

800. Each Defendant owed a duty to Cannon County, and to the public health and safety in Cannon County, because the injuries and harms to the county were foreseeable, and in fact were foreseen by each Defendant.

801. Each of the Marketing Defendants breached those duties by, among other things, promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning their safety and efficacy, and downplaying or omitting the risk of addiction arising from their use.

802. In so doing, the Marketing Defendants acted with actual malice.

803. Cannon County, acting on its own behalf and on behalf of its inhabitants, has suffered, and continues to suffer, both injuries and pecuniary losses directly and proximately caused by the Marketing Defendants' breaches. Among other things, Cannon County has experienced an unprecedented opioid addiction and overdose epidemic costing millions in health insurance, treatment services, autopsies, emergency room visits, medical care, treatment for related illnesses and accidents, payments for fraudulent or medically unnecessary prescriptions and lost productivity to Cannon County's workforce.

804. The Marketing Defendants' breaches of the statutory and common-law duties they each owed to plaintiff and its citizens are the proximate cause of this crisis and its resultant harm to Cannon County and its residents.

## SIXTH CLAIM FOR RELIEF

### Negligence Against All Defendants

805. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

806. Negligence *per se* is established where the defendant violates a statutory duty and where the statute is intended to protect against the result of the violation, the plaintiff is within the class intended to be protected by the statute, and the statutory violation is a proximate cause of the plaintiff's injury. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty and the plaintiff sustained an injury or loss proximately caused by the defendant's breach.

807. To prevail on a negligence claim, a plaintiff must establish (1) a duty of care owed by the defendant to the plaintiff; (2) conduct by the defendant falling below the standard of care amounting to a breach of that duty; (3) an injury or loss; (4) causation in fact; and (5)

proximate or legal cause. *Naifeh v. Valley Forge Life Ins. Co.*, 204 S.W.3d 758, 771 (Tenn. 2006).

808. Each Defendant had an obligation and duty to exercise reasonable care in the manufacturing, marketing and distribution of highly dangerous opioid drugs in and around Cannon County.

809. Each Defendant owed a duty to Cannon County, and to the public health and safety in Cannon County, because the injuries and harms to the county were foreseeable, and in fact were foreseen by each Defendant.

810. All Defendants owed Cannon County, acting on its own behalf and on behalf of its residents, the statutory duty to report suspicious sales, the duty not to fill suspicious orders, the duty to abide by any government agreements entered into regarding the same, and the duty to comply with the federal CSA, 21 C.F.R. § 1301.74(b), which requires the design and operation of a system to detect and disclose suspicious orders of controlled substances.

811. All Defendants owed Cannon County, acting on its own behalf and on behalf of its residents, a duty of care based on Defendants' affirmative acts, described above, that created an unreasonable risk of harm by creating a foreseeable opportunity for wrongful or criminal conduct by third parties. All Defendants realized or should realize that supplying excessive amounts of dangerous, addictive opioids involves an unreasonable risk of harm to another through the conduct of the other or a third person which is intended to cause harm, even though such conduct is wrongful or criminal:

a. All Defendants entrusted prescription opioids capable of doing serious harm if misused, to individuals and entities Defendants knew or had strong reason to believe were likely to misuse it to inflict intentional harm.

b. All Defendants had possession or control of prescription opioids that afforded a peculiar temptation or opportunity for intentional interference

likely to cause harm.

c. All Defendants knew about the likelihood that and other actors, would intentionally divert and/or misuse the prescription opioids, creating a high degree of risk of intentional misconduct.

d. All Defendants had actual or constructive knowledge of each other Defendant's behavior.

812. All Defendants further owed Cannon County a duty of care by virtue of their special relationship as manufacturers, distributors, or dispensers, respectively, of pharmaceutical opioids purchased by Cannon County, and their superior and exclusive knowledge of the dangerous and addictive properties.

813. Each Defendant's conduct foreseeably created a broader zone of risk that poses a general threat of harm to others.

814. Each Defendant's conduct foreseeably and substantially caused the actual injuries to Cannon County.

815. The public policy of Tennessee supports allocating this duty and risk of loss to all Defendants, who are better situated to bear the loss, as opposed to distributing the loss among the general public.

816. All Defendants breached these duties by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances or by failing to report such suspicious orders to the appropriate regulators as required by state and federal law.

817. In so doing, all Defendants acted with actual malice.

818. Cannon County, acting on its own behalf and on behalf of its inhabitants, has suffered, and continues to suffer, both injuries and pecuniary losses directly and proximately caused by all Defendants' breaches. Among other things, Cannon County has experienced an unprecedented opioid addiction and overdose epidemic costing millions in health insurance,

treatment services, autopsies, emergency room visits, medical care, treatment for related illnesses and accidents, payments for fraudulent or medically unnecessary prescriptions and lost productivity to Cannon County's workforce.

819. All Defendants' breaches of the statutory and common-law duties they each owed to plaintiff and its citizens foreseeably and substantially caused the actual injuries alleged herein: they are the proximate cause of this crisis and its resultant harm to Cannon County and its residents.

## SEVENTH CLAIM FOR RELIEF

### Unjust Enrichment Against All Defendants

820. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

821. Unjust enrichment is established where the plaintiff alleges: (a) a benefit conferred upon the defendant by the plaintiff; (b) an appreciation or knowledge by the defendant of the benefit; and (c) the acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without the payment of its value.

822. Cannon County, acting on its own behalf and on behalf of its inhabitants, conferred on each Marketing Defendant a benefit, including, *inter alia*, payments for opioids manufactured by the Marketing Defendants for sale in Cannon County, which benefit was known to and accepted by each Marketing Defendant, which inured to the profits of each Marketing Defendant and for which retention of such benefit is inequitable based on the Marketing Defendants' false and misleading marketing and omissions of and failure to state material facts in connection with marketing opioids, as set forth herein. The Marketing Defendants have thus

been unjustly enriched by sales due to their deceptive marketing, contributing to Cannon County's current opioid epidemic.

823. Cannon County, acting on its own behalf and on behalf of its inhabitants, conferred on each Distributor Defendant a benefit, including, *inter alia*, payments for opioids distributed or filled by each Distributor Defendant for sale in Cannon County, which benefit was known to and accepted by each Distributor Defendant, which inured to the profits of each Supply Chain and for which retention of such benefit is inequitable based on the Distributor Defendants' failure to operate a system to report suspicious orders as required by law and failure to exercise the required care in filling suspicious orders. The Distributor Defendants have thus been unjustly enriched by neglecting their duty to distribute drugs only for proper medical purposes, contributing to Cannon County's current opioid epidemic.

824. Cannon County's unprecedented opioid addiction and overdose epidemic has resulted in substantial costs in health insurance, treatment services, autopsies, emergency visits, medical care, treatment for related illnesses and accidents, payments for fraudulent prescriptions, law enforcement and lost productivity to Cannon County's workforce.

825. The unjust enrichment of all Defendants is directly related to the damage, loss, and detriment to Cannon County caused by Defendants' false marketing and failure to report suspicious sales. It would be inequitable under these circumstances for any of the Defendants to retain this benefit without compensating Cannon County for its value. Cannon County seeks recovery of the amounts the all Defendants were enriched as a result of their inequitable conduct.

## EIGHTH CLAIM FOR RELIEF

### Civil Conspiracy
### Against All Defendants

826. Plaintiff incorporates by reference all other paragraphs of this Complaint as if

fully set forth herein, and further alleges as follows:

827. All Defendants conspired together as more fully alleged in the above causes of action.

828. In pursuance of the conspiracy, all Defendants committed the following overt act(s):

a. All Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful distribution and diversion of opioids into and around Cannon County.

b. Through an express or implied agreement among them, all Defendants were involved in a concerted action to perpetrate a fraud on Plaintiff by the unlawful distribution and diversion of opioids into and around Cannon County.

c. All Defendants acted in furtherance of their agreement which was a concerted action between and among Defendants.

d. Specifically, Marketing Defendants led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe opioids.

e. All Defendants acted with malice, purposefully, unlawfully, and without reasonable excuse.

f. All Defendants' conspiracy to bribe practitioners generated substantial profits for Defendants, their companies, and for co-conspirators.

g. The purpose of the concerted action was to accomplish a criminal or unlawful goal or to accomplish a lawful purpose by the use of criminal or unlawful means.

h. All Defendants unlawfully failed to act to prevent the fraud and failed to monitor, report, and prevent suspicious orders of opioids.

i. All Defendants acted with a common understanding and design to commit unlawful acts as alleged, acted purposefully, without reasonable or lawful excuse, to create injuries alleged herein.

j. All Defendants knew of, or acquiesced in, this wrongful and fraudulent conduct.

829. All Defendants' conspiracy and actions and omissions in furtherance thereof

caused foreseeable losses.

830. All Defendants' conspiracy and acts are also alleged in greater detail, including but without limitation, in Plaintiff's RICO allegations, contained in paragraphs 755 –815 above, and are incorporated herein.

831. Cannon County was damaged as a result of Defendants' conspiracy to commit fraud.

832. All Defendants benefited by this wrongful and fraudulent conduct.

833. All Defendants committed tortious acts in concert with each other and any co-conspirator.

834. As a direct and proximate result of all Defendants' conspiracy and illegal, wrongful or tortious conduct, Cannon County has been damaged. Cannon County, acting on its own behalf and on behalf of its inhabitants, suffered injuries and pecuniary losses as a result of the acts performed pursuant to the conspiracy. Among other things, Cannon County has experienced an unprecedented opioid addiction and overdose epidemic costing millions in health insurance, treatment services, autopsies, emergency room visits, medical care, treatment for related illnesses and accidents, payments for fraudulent or medically unnecessary prescriptions and lost productivity to Cannon County's workforce.

## NINTH CLAIM FOR RELIEF

### Punitive Damages

835. Punitive Damages Against All Defendants

836. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

837. All Defendants were negligent as described in the preceding cause of action.

838. The oversupply of opioids and plague of addiction led to a widespread epidemic of overdoses, illness, and death that claimed thousands of lives and cost many millions of dollars of public spending—circumstances that constituted an imminent or clear and present danger amounting to more than normal and usual peril.

839. All Defendants knew or should have known about the imminent danger posed by continuing to manufacture and/or supply millions of doses of opioids to Cannon County.

840. Notwithstanding Defendants' awareness of the devastating and dangerous consequences of continuing to manufacture and/or supply pharmaceutical opioids to Cannon County, Defendants continued to manufacture and/or supply these pharmaceutical products to Cannon County, demonstrating their conscious disregard of the consequences of these actions. All Defendants' conduct was so reckless and wanting in care that it constituted a conscious disregard and/or indifference to the life, safety, and rights of all those exposed to their conduct in Cannon County.

841. The evidence shows that all the Defendants acted intentionally, recklessly, maliciously and/or fraudulently under Tennessee law to warrant punitive damages.

842. This conduct above directly and proximately caused Cannon County, acting on its own behalf and on behalf of its inhabitants, to suffer injuries and pecuniary losses. Among other things, Cannon County has experienced an unprecedented opioid addiction and overdose epidemic costing millions in health insurance, treatment services, autopsies, emergency room visits, medical care, treatment for related illnesses and accidents, payments for fraudulent or medically unnecessary prescriptions and lost productivity to Cannon County's workforce.

843. Defendants' greed and indifference to the risks caused by their conduct has caused and exacerbated the greatest public health crisis of the modern era. At every opportunity,

Defendants sought to enrich themselves, without regard to the risks their behavior caused others. Defendants had actual knowledge of the wrongfulness of such conduct and the high probability that injury or damage to the County would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in such injury and damage. Defendants' conduct, jointly and severally, was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct, and thereby warranting punitive damages. Defendants' conduct was intentional, reckless, fraudulent, malicious, and deliberately violent or oppressive, and/or committed with such gross negligence as to indicate a wanton and conscious disregard for the rights and safety of others. Accordingly, Defendants are liable for punitive damages.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, Cannon County, Tennessee, acting on behalf of itself and on behalf of its inhabitants, prays that the Court grant the following relief:

A. Enjoin the Distributor Defendants from failing to report suspicious orders as required by the federal CSA;

B. Order all Defendants to pay costs, losses and damages, in excess of $75,000, for injuries sustained by Cannon County, acting on its own behalf and on behalf of its inhabitants, as a proximate result of Defendants' unlawful conduct as set forth herein; and

C. Plaintiff respectfully requests that this Court enter an order of judgment granting all relief requested in this Complaint, and/or allowed at law or in equity, including:

a. abatement of the nuisance;

b. actual damages;

c. declaratory relief;

d. treble or multiple damages and civil penalties as allowed by RICO and other statutes;

e. punitive damages;

f. exemplary damages;

g. disgorgement of unjust enrichment;

h. equitable and injunctive relief, including relief in the form of Court-enforced corrective action, programs, and communications;

i. forfeiture, disgorgement, restitution and/or divestiture of proceeds and assets;

j. attorneys' fees;

k. costs and expenses of suit;

l. pre- and post-judgment interest; and

m. such other and further relief as this Court deems appropriate.

**JURY DEMAND**

Plaintiff respectfully demands a trial by jury on all claims so triable.

Dated: July 6, 2018

*/s/ Mark P. Chalos*
*/s/ Kenneth S. Byrd*

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