IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

EMPLOYER-TEAMSTERS LOCAL NOS. 175 & 505 HEALTH & WELFARE FUND; EMPLOYER-TEAMSTERS LOCAL NOS. 175 & 505 RETIREE HEALTH & WELFARE FUND; TEAMSTERS LOCAL NO. 348 HEALTH & WELFARE FUND; TEAMSTERS UNION LOCAL NO. 52 HEALTH AND WELFARE FUND; AND OHIO CONFERENCE OF TEAMSTERS & INDUSTRY HEALTH AND WELFARE FUND,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; ABBOTT LABORATORIES; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS, LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; INSYS THERAPEUTICS INC.; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; MCKESSON CORPORATION; EXPRESS SCRIPTS HOLDING COMPANY; EXPRESS SCRIPTS, INC.; CVS HEALTH CORPORATION; CAREMARK RX, L.L.C.; CAREMARKPCS HEALTH, L.L.C.; CAREMARK, L.L.C.; UNITEDHEALTH GROUP INCORPORATED; OPTUM, INC.; AND OPTUMRX, INC.,

Case No.

JURY TRIAL DEMANDED

,

Defendants.

COMPLAINT

COME NOW the Plaintiffs, Employer-Teamsters Local Nos. 175 & 505 Health & Welfare Fund, Employer-Teamsters Local Nos. 175 & 505 Retiree Health & Welfare Fund, Teamsters Local No. 348 Health & Welfare Fund, Teamsters Union Local No. 52 Health And Welfare Fund, and Ohio Conference of Teamsters & Industry Health and Welfare Fund (collectively referred to as the "Plaintiffs"), by and through their undersigned counsel, and bring this Complaint against Defendants: Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Abbott Laboratories, Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Mallinckrodt Plc, Mallinckrodt LLC, Allergan PLC f/k/a Actavis PLS, Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis, LLC, Actavis Pharma, Inc. f/k/a/ Watson Pharma, Inc., Insys Therapeutics, Inc., (the "Manufacturer Defendants"); AmerisourceBergen Drug Corporation; Cardinal Health, Inc., and McKesson Corporation (the "Distributor Defendants"); Express Scripts Holding Company, Express Scripts, Inc., CVS Health Corporation, Caremark Rx, L.L.C., CaremarkPCS Health, L.L.C., Caremark, L.L.C., UnitedHealth Group Incorporated, Optum, Inc., and OptumRX, Inc. (the "PBM Defendants"), (collectively "Defendants"). Plaintiffs sue Defendants and allege as follows:

INTRODUCTION

1. Plaintiffs, union health and welfare benefit funds, bring this Complaint against Defendants for their responsibility in the creation and perpetuation of the health crisis related to the manufacture, marketing, sale and distribution of prescription opioids. At all relevant times, Plaintiffs have paid and/or provided reimbursement on behalf of its members and their dependents for some or all of the purchase price of prescription opioids manufactured, marketed, promoted, sold, distributed, and/or authorized for reimbursement by the Defendants, pharmaceutical manufacturers, wholesalers/distributors, and pharmacy benefit managers (PBMs). Plaintiffs have also paid and/or provided reimbursement for health care claims associated with opioid dependence, abuse and addiction.

2. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative cancer or end-of-life care. Barring exceptional circumstances; however, opioids are too addictive[1] and too debilitating for long-term use for chronic, non-cancer pain lasting three months or longer ("chronic pain"). This is due in part because the effectiveness of opioids wanes with prolonged use, requiring ever higher doses to achieve pain relief. This markedly increases the risk of addiction.[2] Indeed, the U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[3]

3. Despite having the foregoing knowledge, the Manufacturer Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that encouraged the use of opioids for longer periods of

[1] Substance use disorders range from misuse and abuse of drugs to addiction. *See* Am. Psych. Ass'n, *What is Addiction*, Psychiatry, https://www.psychiatry.org/patients-families/addiction/what-is-addiction (last visited Mar. 23, 2018). Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.
[2] *See, e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 PROGRESS IN PAIN RES. & MGMT., 247287 (H.L. Fields and J.C. Liebeskind eds., 1994).
[3] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

time for a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches. The Manufacturer Defendants encouraged that false perception through a coordinated, sophisticated, and highly deceptive scheme that began in the late 1990s, became more aggressive in or about 2006, and continues to the present.

4. The Distributor Defendants could have and should have been able to stem the excess flow of opioids, but they did not. Wholesale drug distributors receive prescription opioids from drug manufacturers and transfer the opioids to hospitals, pharmacies, doctors, and other healthcare providers who then dispense the drugs to patients. Distributors are required by federal and state law to control and report unlawful drug diversions. The Distributor Defendants purposefully ignored these responsibilities, lobbied for higher reporting thresholds and pocketed profits at the expense of Plaintiffs.

5. The PBM Defendants are the gatekeepers to the vast majority of opioid prescriptions filled in the United States. PBMs control drug formularies which set the criteria and terms under which pharmaceutical drugs are reimbursed. In this way, PBMs control prescription drug utilization overall and are the middlemen between the manufacture and the availability of opioids. Even though the PBM Defendants were well aware of the effect of their decisions about formulary placement, they chose to make decisions purely for their own financial gain.

6. Each Defendant group bears culpability for the current national opioid crisis and is a necessary party to addressing the damage it has wreaked, including the costs of abatement.

7. The Defendants' scheme has been extremely harmful to this country, without achieving any material health benefit. Opioid addiction and overdose have reached

epidemic levels over the past decade. On March 22, 2016, the U.S. Food and Drug Administration ("FDA") recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."[4] Opioid-related overdose deaths in 2015 far outnumbered deaths from either auto accidents or guns.[5] Drug overdoses in 2017 roughly equaled the number of Americans who died in the Vietnam, Iraq, and Afghanistan wars combined.[6] The rising numbers of persons addicted to opioids also have led to significantly increased health care costs as well as a dramatic increase of social problems throughout the United States, including drug abuse and diversion.[7] Yet, since 1999, there has been no overall change in the amount of pain that Americans report.[8]

8. The International Brotherhood of Teamsters ("the Teamsters") and its members have been profoundly affected by the opioid epidemic. Formed in 1903, the Teamsters are known as the champion of freight drivers and warehouse workers, but have organized workers in virtually every occupation imaginable, both professional and non-professional, private sector and public sector.

9. Plaintiffs' members specifically come from physically demanding and high-risk industries, like construction, manufacturing, and warehousing, that the opioid epidemic has hit particularly hard. Opioid use, dependence, and addiction is closely intertwined with physical labor. Workers go to the doctor due to workplace-related injuries, are prescribed

[4] FDA News Release, FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death (Mar. 22, 2016), *available at* http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm.
[5] *Drug Overdoses Killed 50,000 in U.S., More Than Car Crashes*, NBCNEWS, Dec. 9, 2016, https://www.nbcnews.com/health/health-news/drug-overdoses-killed-50-000-u-s-more-car-crashes-n694001.
[6] Nicholas Kristof, *Opioids, a Mass Killer We're Meeting With a Shrug*, N.Y. TIMES, Jun. 22, 2017, https://www.nytimes.com/2017/06/22/opinion/opioid-epidemic-health-care-bill.html.
[7] According to the CDC, "When prescription medicines are obtained or used illegally, it is called drug diversion." *Risks of Healthcare-associated Infections from Drug Diversion*, CDC, https://www.cdc.gov/injectionsafety/drugdiversion/index.html (last updated Oct. 27, 2017).
[8] *Understanding the Epidemic: Drug overdose deaths in the United States continue to increase in 2016*, CDC, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Aug. 30, 2017) (hereinafter "*Understanding the Epidemic*").

opioids for pain, and then become reliant on them to be able to continue working.[9]

10. Opioid use by workers in high-risk industries has tangible financial and personal costs. For example, spending on prescription opioids is consistently 510% higher in construction than any other industry, and also elevated in manufacturing industries.[10] Workers in these same industries are also at an especially high risk of dying from an opioid overdose.[11]

11. Plaintiffs, Teamster health and welfare funds, provide healthcare coverage for millions of active and retired Teamsters and their dependents (collectively, "insureds"), and spend billions of dollars on covered medical expenses annually. In this role, Plaintiffs directly bear much of the financial cost of opioid use, dependence, abuse, and addiction by and among their insureds.

12. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiffs have incurred costs for opioid prescriptions in excess of those they would have otherwise incurred, and have incurred and will continue to incur costs associated with opioid abuse, dependence, and addiction, including payments for emergency and hospital care to treat opioid abuse and overdose by their insureds, as well as payments for their insureds' treatment for opioid addiction. Defendants' scheme to increase long-term opioid use proximately caused injury to Plaintiffs.

JURISDICTION AND VENUE

[9] *See, e.g.*, Nicholas Wyman, *America's Workforce Is Paying A Huge Price For The Opioid Epidemic*, FORBES, Dec. 12, 2017, https://www.forbes.com/sites/nicholaswyman/2017/12/12/americas-workforce-is-paying-a-huge-price-for-the-opioid-epidemic/#7358db0b71bd; Quentin Fottrell, *Americans struggling with opioid addiction miss 50% more work than everyone else*, MARKETWATCH, Oct. 28, 2017, https://www.marketwatch.com/story/americas-prescription-drug-epidemic-is-a-worsening-problem-for-employers-2017-03-13.

[10] Wyman, *supra* note 9.

[11] Doug Livingston, *Summit County jobless and Ohio construction workers are top casualties in opioid crisis*, BEACON JOURNAL/OHIO.COM (Nov. 11, 2017, 10:10PM), https://www.ohio.com/akron/news/local/summit-county-jobless-and-ohio-construction-workers-are-top-casualties-in-opioid-crisis (last updated November 13, 2017, 1:58PM); Rachel Dissell, *Ohio construction workers seven times more likely to die of an opioid overdose in 2016*, THE PLAIN DEALER (Nov. 5, 2017), http://www.cleveland.com/metro/index.ssf/2017/11/ohio_construction_workers_seven_times_more_likely_to_die_of_an_opioid_overdose_in_2016.html (last updated Jan. 19, 2018).

13. 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"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

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

15. This Court also has personal jurisdiction over all defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts.[12] Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.

16. 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.

PARTIES

Plaintiffs

17. Employer-Teamsters Local Nos. 175 & 505 Health & Welfare Fund and

[12] *See, e.g. Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris Inc.*, 23 F. Supp. 796, 803 (E.D. Ohio 1998).

Employer-Teamsters Local Nos. 175 & 505 Retiree Health & Welfare Fund (collectively referred to as "Local 175 & 505") is a non-profit, self-funded health and welfare benefit plan covering union members and their families. Its principal place of business is in Charleston, West Virginia, and covers union members in Ohio. Local 175 & 505 covers approximately 858 active union members and 902 retirees as well as their families — totaling over 3,900 lives. Local 175 & 505 provides health benefits, including prescription drug benefits, to its insureds. Throughout all relevant times herein, Local 175 & 505 indirectly purchased, paid, and reimbursed for opioids intended for consumption by its insureds, and paid for the health care costs resulting from its insureds' dependence on, abuse of, and addiction to opioids. Given its insureds' past use of opioids, Local 175 & 505 anticipates that it will continue to pay for such health care costs in the future.

18. Teamsters Local No. 348 Health & Welfare Fund ("Local 348") is a non-profit, self-funded health and welfare benefit plan covering employees, retirees, and their families. Its principal place of business is in Cleveland, Ohio. Local No. 348 covers approximately 398 active and retired union members as well as their families — totaling over 1,047 lives. Local 348 provides health benefits, including prescription drug benefits, to its insureds. Throughout all relevant times herein, Local 348 indirectly purchased, paid, and reimbursed for opioids intended for consumption by its insureds, and paid for the health care costs resulting from its insureds' dependence on, abuse of, and addiction to opioids. Given its plan members' past purchases of opioids, Local 348 anticipates that it will continue to pay for such health care costs in the future.

19. Teamsters Union Local No. 52 Health And Welfare Fund ("Local 52") is a non-profit, self-funded health and welfare benefit plan covering employees, retirees, and their

families. Its principal place of business is in Cleveland, Ohio. Local No. 52 covers approximately 250 active and retired union members as well as their families — totaling over 350 lives. Local 52 provides health benefits, including prescription drug benefits, to its insureds. Throughout all relevant times herein, Local 52 indirectly purchased, paid, and reimbursed for opioids intended for consumption by its insureds, and paid for the health care costs resulting from its insureds' dependence on, abuse of, and addiction to opioids. Given its plan members' past purchases of opioids, Local 52 anticipates that it will continue to pay for such health care costs in the future.

20. Ohio Conference of Teamsters & Industry Health and Welfare Fund ("Ohio Conference") is a non-profit, self-funded health and welfare benefit plan covering employees, retirees, and their families. Its principal place of business is in Toledo, Ohio. The Ohio Conference covers approximately 2,707 active and retired union members as well as their families — totaling over 7,000 lives. The Ohio Conference provides health benefits, including prescription drug benefits, to its insureds. Throughout all relevant times herein, the Ohio Conference indirectly purchased, paid, and reimbursed for opioids intended for consumption by its insureds, and paid for the health care costs resulting from its insureds' dependence on, abuse of, and addiction to opioids. Given its plan members' past purchases of opioids, the Ohio Conference anticipates that it will continue to pay for such health care costs in the future.

Defendants

A. MANUFACTURER DEFENDANTS

Purdue and Associated Companies

21. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. It is owned principally by parties and descendants of Mortimer and Raymond Sackler.

22. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

23. Defendant The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

24. At all relevant times, Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company, Inc. (collectively, "Purdue Pharma") are or have been in the business of manufacturing, selling, promoting, and/or distributing opioids throughout the United States, including OxyContin, MS Contin, Dilaudid, Dilaudid-HP, Butrans, Hysingla ER, and Targiniq ER.

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

Abbott Laboratories and Associated Companies

26. Abbott Laboratories is a domestic corporation organized under the laws of the State of Illinois with its principal place of business in Abbott Park, Illinois. Abbott Laboratories, Inc., is an Illinois corporation with its principal place of business in Abbott Park, Illinois. (Collectively, "Abbott.")

27. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to a co-promotional agreement with Defendant Purdue Pharma. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue Pharma's Opioid products as set forth below.

Cephalon and Associated Companies

28. Defendant Cephalon, Inc. is a Delaware corporation with its principal

place of business in Frazer, Pennsylvania.

29. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals Ltd. acquired Cephalon in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Teva Pharmaceuticals Ltd.

30. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. in Pennsylvania.

31. Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Cephalon") are in the business of manufacturing, selling, promoting, and/or distributing brand name opioids throughout the United States, including Actiq and Fentora. Cephalon also was in the business of selling generic opioids, including a generic form of OxyContin, from 2005 to 2009 nationally.

Janssen, Johnson & Johnson and Associated Companies

32. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

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

34. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

35. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of Johnson & Johnson until July 2016. Noramco, Inc. is or had been part of Johnson & Johnson's opium processing by making

active pharmaceutical ingredients ("APIs") for opioid painkillers.

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

37. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

38. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals' stock. Johnson & Johnson controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to Johnson & Johnson's benefit.

39. Johnson & Johnson, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including Duragesic, Nucyntra,[13] and Nucyntra ER. 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.

Endo and Associated Companies

40. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

41. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

42. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively,

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

"Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including the following Opana ER, Opana, Percodan, and Percocet. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also is or has been in the business of manufacturing, selling, promoting, and/or distributing generic opioids through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

Mallinckrodt and Associated Companies

43. Defendant Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri.

44. Defendant Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, Plc. Mallinckrodt, Plc and Mallinckrodt, LLC (collectively, "Mallinckrodt") are or have been in the business of manufacturing, selling, promoting, and/or distributing opioids, including Roxicodone and oxycodone, throughout the United States.

Allergan and Associated Companies

45. Defendant Allergan Plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland.

46. Defendant Actavis Plc acquired Defendant Allergan Plc in March 2015; however, the combined company changed its name to Allergan Plc in January 2013.

47. Defendant Watson Pharmaceuticals, Inc. acquired Defendant Actavis, Inc. in October 2012. The combined company changed its name to Actavis, Inc. as of January 2013

and then changed the name to Actavis Plc in October 2013.

48. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Defendant Allergan Plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

49. Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

50. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

51. Each of these defendants is owned by Defendant Allergan Plc, which uses them to market and sell its drugs in the United States. Defendant Allergan Plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan Plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, "Allergan") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana.

Insys

52. Insys Therapeutics, Inc. ("Insys") is a Delaware company with its principal place of business in Chandler, Arizona. Insys is or has been in the business of manufacturing, selling, promoting, and/or distributing opioids, including fentanyl-based cancer spray, Subsys.

B. DISTRIBUTOR DEFENDANTS

AmerisourceBergen

53. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania. AmerisourceBergen is the second largest pharmaceutical distributor in North America.

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

55. AmerisourceBergen does substantial pharmaceutical business in Ohio.

Cardinal Health

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

57. In 2016, Cardinal Health generated revenues of $121.5 billion

58. Cardinal Health has, at all relevant times, distributed opioids nationwide and does substantial pharmaceutical business in Ohio.

McKesson

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

60. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America.

61. For the fiscal year ending March 31, 2017, McKesson generated revenues of $198.5 Billion.

62. In its 2017 Annual Report, McKesson states that it "partner[s] with

pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively."

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

64. McKesson is the largest pharmaceutical distributor in the United States. McKesson has more than 40,000 customers nationally. McKesson does substantial pharmaceutical business in Ohio.

65. Collectively, McKesson, AmerisourceBergen and Cardinal Health account for 85% of the drug shipments in the United States. These companies together collect about $400 billion in annual revenue.

66. The Distributor Defendants purchased opioids from manufacturers, such as the Manufacturer Defendants herein, and sold them to pharmacies that served Plaintiffs' insureds. The Distributor Defendants played an integral role in opioids being distributed to Plaintiffs' insureds.

67. The failure of all Distributor Defendants to effectively monitor and report suspicious orders of prescription opioids and to implement measures to prevent the filling of invalid and medically unnecessary prescriptions greatly contributed to the vast increase in opioid overuse and addiction.

C. PBM DEFENDANTS

Express Scripts

68. Defendant, Express Scripts Holding Company ("ESHC"), is a Delaware

corporation with its principal place of business in St. Louis, Missouri.

69. Defendant, Express Scripts, Inc. ("ESI"), is incorporated in the State of Delaware with its principal place of business located in St. Louis, Missouri. ESI is a pharmacy benefit management company, and is a wholly-owned subsidiary of ESHC.

70. ESHC and ESI are collectively referred to as "Express Scripts."

71. In 2012, ESI acquired its rival, Medco Health Solutions Inc., in a $29.1 billion deal. As a result of the merger, ESHC was formed and became the largest PBM in the nation, filing a combined 1.4 billion prescriptions for employers and insurers.[14]

72. According to the Pharmacy Benefit Management Institute, in 2017, Express Scripts was the second ranking PBM nationwide with twenty-four percent (24%) of the industry market share.[15]

73. Express Scripts derives substantial revenue managing pharmacy benefits in Ohio through several different means, including, but not limited to, providing services and formulary to certain Plaintiffs. During much of the relevant period of this complaint, ESI provided services and formulary to certain Plaintiffs.

CVS Health and Associated Companies

74. Defendant, CVS Health Corporation ("CVS Health"), formerly known as CVS Caremark Corporation, is a Delaware corporation with its principal place of business located in Woonsocket, Rhode Island.

75. Defendant, Caremark Rx, L.L.C., is a Delaware limited liability company

[14] Peter Frost, *Express Scripts closes $29.1-billion purchase of Medco*, L.A. TIMES, Apr. 3, 2012, http://articles.latimes.com/2012/apr/03/business/la-fi-medco-20120403.
[15] *Industry Research: PBM Market Share*, Pharm. Benefit Mgmt. Inst., https://www.pbmi.com/PBMI/Research/Industry_Research/PBMI/Research/PBMI___Industry_Research.aspx?hkey=22023612-80c4-4ada-a17e-85e7dfcbc1f8 (last visited Mar. 23, 2018).

whose principal place of business is at the same location as CVS Health. On information and belief, CVS Health is the direct parent company of Caremark Rx, L.L.C. According to CVS Health's 2016 Annual Report, "[CVS Health]'s pharmacy services subsidiaries, is the immediate or indirect parent of many mail order, pharmacy benefit management, infusion, Medicare Part D, insurance, specialty mail and retail specialty pharmacy subsidiaries, all of which operate in the United States and its territories."

76. Defendant, CaremarkPCS Health, L.L.C., is a Delaware limited liability company doing business as CVS/Caremark and CVS Caremark and whose principal place of business is at the same location as CVS Health. On information and belief, CVS Health is the direct or indirect parent company of CaremarkPCS Health, L.L.C.

77. Defendant, Caremark, L.L.C., is a California limited liability company whose principal place of business is at the same location as CVS Health. Defendant, Caremark PCS, L.L.C., is a Delaware limited liability company formerly known as AdvancePCS Inc., which was founded in 1996 and is based in Irving, Texas. On information and belief, Caremark Rx, L.L.C. is the sole member of both Caremark, L.L.C. and CaremarkPCS, L.L.C.

78. Defendants Caremark RX, L.L.C., CaremarkPCS HEALTH, L.L.C., Caremark, L.L.C. and Caremark PCS, L.L.C. are collectively referred to as "Caremark."

79. CVS Health describes itself in a September 3, 2014 press release as a "pharmacy innovation company helping people on their path to better health. Through our 7,700 retail pharmacies, 900 walk-in medical clinics, a leading pharmacy benefits manager with nearly 65 million plan members, and expanding specialty pharmacy services, we enable people, businesses and communities to manage health in more affordable, effective ways. This unique integrated model increases access to quality care, delivers better health outcomes and lowers

overall health care costs."[16] In 2016, CVS Health reported an operating income of $10 billion.

80. In the above-referenced September 3, 2014 press release CVS Health announced its change of name from CVS Caremark Corporation to CVS Health. CVS Health explained that it was changing its name "to reflect its broader health care commitment and its expertise in driving the innovations needed to shape the future of health."[17] CVS Health explained that the newly-named company included "its pharmacy benefit management business, which is known as CVS/Caremark."[18] In that same press release, CHS Health touted, "[f]or our patients and customers, *health is everything* and…we are advising on prescriptions [and]helping manage chronic and specialty conditions."[19]

81. According to the Pharmacy Benefit Management Institute, CVS Health (Caremark) was the highest ranking PBM in 2017 with 25% of the industry market share.[20]

82. At all times relevant hereto, CVS Health and Caremark offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Ohio.

83. At all times relevant hereto, CVS Health, through Caremark, derives substantial revenue providing pharmacy benefits through several different means including, but not limited to, providing services and formulary to certain of the Plaintiffs.

84. At all times relevant hereto, Caremark has served as the PBM for certain of the Plaintiffs and has reimbursed for opioids in Ohio.

UnitedHealth and Associated Companies

[16] Press Release, CVS Caremark Announces Corporate Name Change to CVS Health to Reflect Broader Health Care Commitment, CVSHealth (Sept. 3, 2014), https://cvshealth.com/newsroom/press-releases/cvs-caremark-announces-corporate-name-change-cvs-health-reflect-broader.
[17] *Id*.
[18] *Id.*
[19] *Id*. (emphasis added).
[20] Pharm. Benefit Mgmt. Inst., *supra* note 15.

85. Defendant, UnitedHealth Group Incorporated ("UnitedHealth"), a Delaware corporation with its principal place of business located in Minnetonka, Minnesota, is a diversified managed health care company with two business platforms. UnitedHealth serves approximately 115 million individuals throughout the United States. For 2016, UnitedHealth reported an operating income of $12.9 billion.

86. Defendant, Optum, Inc., is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth's pharmacy benefits, including OptumRX, Inc. On information and belief, Optum, Inc. is a subsidiary of UnitedHealth.

87. Defendant, OptumRX, Inc. ("OptumRx"), is a Delaware corporation with its principal place of business located in Irvine, California. OptumRx operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of Optum, Inc. OptumRx operates as the PBM for UnitedHealth.

88. According to the Pharmacy Benefit Management Institute, OptumRx (UnitedHealth) was the third highest ranking PBM in 2017 with 22% of the industry market share.[21]

89. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Ohio.

90. At all times relevant hereto, OptumRx derives substantial revenue providing pharmacy benefits through several different means including, but not limited to, providing services and formulary to certain of the Plaintiffs.

91. At all times relevant hereto, OptumRx has served as the PBM for certain

[21] Pharm. Benefit Mgmt. Inst., *supra* note 15.

of the Plaintiffs and has reimbursed for opioids in Ohio.

FACTUAL ALLEGATIONS

A. Prescription Opioids

92. The term opioid includes (a) all drugs derived in whole or in part from the morphine-containing opium poppy plant such as morphine, laudanum, codeine, thebaine, hydrocodone oxycodone and oxymorphone, and (b) synthetic opioids like fentanyl or methadone.

93. Opioids are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous and therefore are regulated by the federal government as controlled substances.

94. Since passage of the Controlled Substances Act ("CSA") in 1970, controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have "a high potential for abuse," have "a currently accepted medical use," and "may lead to severe psychological or physical dependence."[22] Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA.[23] The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an

[22] 21 U.S.C. § 812(b)(2).
[23] 21 U.S.C. § 829.

excessive dose.[24]

95. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are "frighteningly high."[25] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

96. 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.

97. During much of the latter half of the 20th century, doctors used opioid pain relievers sparingly, and only in the short term, for cases of acute injury or illness, during and immediately after surgery, or for palliative cancer or end-of-life care. Opioids provide effective treatment for this type of care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Doctors' reluctance to use opioids for an extended period was due to the legitimate fear of causing addiction.[26]

98. Beginning in the late 20th century, however, and continuing through

[24] *See, e.g.*, March 22, 2016, Required Safety Labeling Language for Immediate Release Opioids, FDA, https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM491594.pdf.
[25] M. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170 ARCHIVES OF INTERNAL MED. 1422 (2010).
[26] PROGRESS IN PAIN RESEARCH AND MANAGEMENT, VOL. 25 (M.L. Meldrum ed., 2003).

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

99. As set forth below, the Defendants facilitated this expansion in three ways. First, the Manufacturer Defendants engaged in a misinformation campaign which altered public perception of opioids, and deceived doctors, federal regulators, and the public about their addictive qualities. Second, PBM Defendants ensured that opioids were widely available, regularly prescribed and reimbursed for chronic pain. Third, Manufacturer and Distributor Defendants violated their federally imposed requirements to report suspicious opioid orders to the DEA and state agencies. These facilitated an explosion in the illegitimate marketplace for prescription opioids.

100. Because of Defendants' wrongful conduct, the number of prescriptions for opioids increased sharply, reaching nearly 250 million prescriptions in 2013, almost enough for every adult in the United States to have a bottle of pills.[27] Between 1999 and 2015, the amount of opioids prescribed per person had increased 300% , from 180 to 640 morphine milligram equivalents ("mme," a standard reference measure of strength for various opioids) .[28] This occurred despite no overall change in the amount of pain that Americans reported over a similar

[27] *Opioid Painkiller Prescribing*, CDC Vital Signs (July 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/index.html.
[28] *Opioid Prescribing: Where you live matters*, CDC Vital Signs (July 2017), https://www.cdc.gov/vitalsigns/pdf/2017-07-vitalsigns.pdf.

period (1999 to 2010).[29]

101. Prescription opioid drug spending increased by similar proportions from 1999 to 2012. Americans collectively spent $2.3 billion on prescription opioids in 1999. By 2006, spending had almost tripled to more than $7.0 billion.[30] Ten years later, in 2016, opioid sales totaled $8.6 billion and continue to rise.[31]

102. But while the numbers of opioid prescriptions and total spending have increased, patients' share of the costs of opioids has significantly decreased as insurers and other third-party payors, including union health and welfare funds such as Plaintiffs, have assumed a greater share of prescription drug expenditures. CDC researchers now believe that public and private insurers pay most prescription drug costs for opioid pain relievers. Using data from the Medical Expenditure Panel Survey to examine trends in opioid prescribing and expenditures by payor type, the researchers found that patient out-of-pocket spending on opioids per 100 mme declined from $4.40 in 2001 to 90 cents in 2012, with insurers paying an increasingly larger share of the cost. Whereas in 1999, 53% of spending on opioid pain relievers came from patients paying out-of-pocket, by 2012, out-of-pocket spending had declined to 18% of all expenditures.[32]

103. The increase in spending on opioid prescriptions demonstrates the success of the Defendants' scheme. Defendants were aware that significantly expanding the marketplace for opioids depended in part on ensuring the comprehensive coverage of opioids by insurers and third-party payors. Defendants knew that their goal of increasing profits by promoting the

[29] *Understanding the Epidemic*, *supra* note 8.
[30] Tracey Walker, *New payer trends for opioids coincide with epidemic*, MANAGED HEALTHCARE EXEC., May 10, 2016, http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/new-payer-trends-opioids-coincide-epidemic.
[31] Haley Sweetland Edwards, *The Drug Cascade*, TIME, June 22, 2017, http://time.com/4828108/the-drug-cascade/.
[32] Walker, *supra* note 30.

prescription of opioids for chronic pain would lead directly to an increase in health care costs for health care payors, such as Plaintiffs.

B. The Opioid Epidemic

104. Opioid dependence, abuse, and addiction has become a national epidemic and public health emergency, with particular populations hit especially hard.

105. One manifestation of the epidemic is dramatic increases in the number of opioid-related drug overdoses, many fatal. For example, nationwide from 1990 to 2015 the average consumption of hydrocodone nationwide increased by 300%, while in the same period, there was a 500% increase in the number of Emergency Department visits attributed to hydrocodone abuse.[33] And, according to the CDC, opioids were responsible for 42,000 deadly drug overdoses in 2016, reflecting a fivefold increase since 1999.[34] Worse yet, these numbers are likely underestimates, as a recent study found that the government is undercounting opioid overdose deaths by 2035%.[35] Recent CDC data also indicated emergency room visits for suspected opioid overdoses increased by approximately 30% from July 2016 to September 2017.[36]

106. In Ohio, home to 50,000 Teamsters members, opioids have become the main source of drug overdoses. Due to the vast supply of opioids, in 2007, unintentional drug-

[33] *Hydrocodone Addiction*, CRC Health, http://www.crchealth.com/addiction/drug-addiction-rehab/drug-addiction-rehab-2/home-2/hydrocodone_addiction/ (last visited Mar. 23, 2018).
[34] *Opioid Overdose: Drug Overdose Death Data*, CDC, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last updated Dec. 19, 2017).
[35] Keith Humphreys, *The government has been undercounting opioid overdose deaths up to 35 percent, study says*, WASH. POST. (Mar. 12, 2018), https://www.washingtonpost.com/news/wonk/wp/2018/03/12/the-government-has-been-undercounting-opioid-overdose-deaths-up-to-35-percent-study-says/?utm_term=.07dc03e6f1bf.
The government has been undercounting opioid overdose deaths up to 35 percent, study says, Washington Post, Mar. 12, 2018, https://www.washingtonpost.com/news/wonk/wp/2018/03/12/the-government-has-been-undercounting-opioid-overdose-deaths-up-to-35-percent-study-says/?utm_term=.412a9544c449.
[36] Alana M. Vivolo-Kantor et al., *Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017*, 67 MORBIDITY & MORTALITY WKLY. REP. 279, 285 (Mar. 9, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6709e1-H.pdf.

related overdoses surpassed car accidents as the leading cause of accidental death in Ohio.[37] Since then, overdose rates have continued to grow despite numerous city and county health commissioners declaring opioids a public health emergency. In 2016, Ohio saw a 36% increase in unintentional fatal overdoses from the previous year, and led the nation in the total number of fatal overdoses.[38] Accidental ingestions of opioids by children have also increased, more than doubling to some 200 intoxications a year in Dayton, Ohio, for example.[39]

107. Construction workers, including carpenters, ironworkers, roofers, and road crew workers, are at particularly high risk of dying from opioid overdose. In Ohio, for example, construction workers were seven times more likely to die from an opioid overdose than other professions.[40] This is not random. Construction workers and, to a lesser but still meaningful extent, other workers in physically demanding and high-risk jobs like transportation, mining and manufacturing, are commonly prescribed opioids to treat on-the-job injuries. In 2010, for example, more than 80% of construction workers who filed on-the-job injury clams with the Bureau of Workers Compensation and were treated with medications were prescribed narcotics, often opioids such as Vicodin, Percocet and OxyContin. In 2016, even after the Bureau introduced new standards to reduce the overprescribing of opioids, 73% of injured construction workers still received a narcotic prescription.[41]

108. Even when not fatal, opioid dependence, abuse, and addiction is injuring patients and increasing health care costs. For example, one study revealed that hospitalizations

[37] Kimiko de Freytas-Tamura, *Amid Opioid Overdoses, Ohio Coroner's Office Runs Out of Room for Bodies*, N.Y. TIMES, Feb. 2, 2017, https://www.nytimes.com/2017/02/02/us/ohio-overdose-deaths-coroners-office.html.
[38] *Newspaper: Ohio had more than 4,000 overdose deaths in 2016*, THE COLUMBUS DISPATCH, May 28, 2017, http://www.dispatch.com/news/20170528/newspaper-ohio-had-more-than-4000-overdose-deaths-in-2016.
[39] Julie Turkewitz, *'The Pills Are Everywhere': How the Opioid Crisis Claims Its Youngest Victims*, N.Y. TIMES, Sept. 20, 2017, https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html.
[40] Dissel, *supra* note 11; *see also Opioid overdose deaths: Which jobs are at risk?*, THE PLAIN DEALER, Nov. 5, 2017, http://www.cleveland.com/metro/index.ssf/2017/11/opioid_overdose_deaths_which_j.html.
[41] Dissel, *supra* note 11.

related to opioid abuse and dependence rose by 72% (301,707 to 520,275) from 2002 to 2012, while overall hospitalizations remained largely consistent (36.52 million to 36.48 million). Opioid-related hospitalizations with serious infection jumped 91% to 6,535 over the ten-year period reviewed.[42]

109. The cost of opioid-related hospitalizations is also increasing. Studies have shown that the average cost of care per opioid-related admission has dramatically increased between 2009 and 2015, from $58,500 to $92,400,[43] and that the cost to treat people who are dependent on or abuse opioids is far greater than ordinary patients.[44] This is due in part to the fact that patients entering the hospital due to overdose need to be sedated and on ventilation for long periods of time and also are often suffering other ill-effects from drug use, such as liver and kidney failure. Total inpatient charges related to opioid abuse and dependence reached $14.85 billion in 2012, more than four times the total in 2002.[45]

110. The rates of neonatal abstinence syndrome, which occurs when a baby is born addicted to opioids, have also increased dramatically.[46] Nationally, the cost of treating neonatal abstinence syndrome increased from $61 million in 2003 to nearly $316 million in 2012.[47]

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[42] CJ Arlotta, *How Opioid Abuse Contributes to Rising Healthcare Costs*, FORBES, May 3, 2016, https://www.forbes.com/sites/cjarlotta/2016/05/03/opioid-abuse-contributes-to-rising-health-care-costs/#1fae561173a3.

[43] Casey Ross, *The cost of Treating opioid overdose victims is skyrocketing*, STATNEWS, Aug. 11, 2017, https://www.statnews.com/2017/08/11/opioid-overdose-costs/

[44] *Counting the cost of opioid abuse*, Optum, https://www.optum.com/resources/library/counting-cost-of-opioid-abuse.html (last visited Nov. 15, 2017).

[45] Cara Livernois, *Hospitalizations for opioid abuse double, costs quadruple in 10 years*, HEALTHEXEC, May 3, 2016, http://www.healthexec.com/topics/policy/hospitalizations-opioid-abuse-double-costs-quadruple-10-years.

[46] Hannah Rappleye et al., *Born Addicted: The Number of Opioid-Addicted Babies is Soaring*, NBCNEWS, Oct. 9, 2017, https://www.nbcnews.com/storyline/americas-heroin-epidemic/born-addicted-number-opioid-addicted-babies-soaring-n806346; *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (last updated Sept. 2015).

[47] T.E. Corr & C.S. Hollenbeak, *The economic burden of neonatal abstinence syndrome in the United States*, 112 Addiction 1590 (Sept. 2017), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1111/add.13842.

111. Abuse of prescription opioids is also inextricably intertwined with the resurgence of heroin use and recent HIV and Hepatitis C outbreaks.[48] Approximately three out of four new heroin addicts in the United States started by abusing prescription opioids.[49] Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost $10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. The costs associated with infections associated with injection drug use are not insignificant. For example, one study of 302 Florida hospitals found that "[c]harges for hepatitis C patients who used opiates were $731,000 a day higher in 2015 than in 2010, coinciding with the 171 percent rise in heroin and opium overdoses."[50] And, while Hepatitis C is curable, the list price for a single course of treatment reaches as high as $94,500.[51]

112. Rates of opioid addiction have also skyrocketed. One analysis by Blue Cross Blue Shield of its commercially insured members found that the number of people addicted to opioids increased nearly five-fold from 2010 to 2016.[52] Other studies have found that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[53] And national data shows that 2.1 million people had an opioid use disorder in 2016,

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[48] *See, e.g.*, Jon E. Zibbell, et al., *Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged ≤30 Years — Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012*, 64 MORBIDITY & MORTALITY WKLY. REP. 453 (May 8, 2015), https://www.cdc.gov/mmwr/pdf/wk/mm6417.pdf.

[49] Pradip K. Muhuri et al., *Associations of nonmedical pain reliever use and initiation of heroin use in the United States*, CBHSQ DATA REV. (Aug. 2013), https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm.

[50] Pat Beall & Mike Stucka, *Cost of heroin epidemic tops $1 billion a year in Florida*, MYPALMBEACHPOS, Dec. 17, 2016, http://www.mypalmbeachpost.com/news/cost-heroin-epidemic-tops-billion-year-florida/WYamI7pzwlHMkFkf3mzY8H/.

[51] Laurie Toich, *Will Hepatitis C Virus Medication Costs Drop in the Years Ahead*, PHARMACY TIMES, Feb. 8, 2017, http://www.pharmacytimes.com/resource-centers/hepatitisc/will-hepatitis-c-virus-medicaton-costs-drop-in-the-years-ahead.

[52] *The Health of America: America's opioid epidemic and its effect on the nation's commercially-insured population*, BlueCross Blue Shield (June 29, 2017), https://www.bcbs.com/the-health-of-america/reports/americas-opioid-epidemic-and-its-effect-on-the-nations-commercially-insured (hereinafter "*The Health of America*").

[53] J. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30 J. ADDICTIVE DISEASES 185 (2011); J. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105 ADDICTION 1776 (2010).

and that 11.5 million people misused prescription opioids that year.[54] Treating opioid addiction is possible, and addiction treatment rates are increasing but at a much slower rate than addiction itself.[55] Accordingly, significant investments are still needed in addiction treatment to resolve the opioid crisis.

113. The National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include dramatic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by pharmaceutical companies."[56] As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes " are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."[57]

C. The Manufacturer Defendants' Misinformation Campaign

114. During the 1980s and 1990s, the brand name drug Manufacturer Defendants grew unsatisfied with the market for opioid use in the context of acute and palliative care. To increase the number of people taking opioids, they introduced new opioid drugs and began promoting their use for chronic pain therapy. The generic drug Manufacturer Defendants were at all times aware of and profited from the misinformation campaign of the brand name drug Manufacturer Defendants as set forth herein and did nothing to correct such misinformation

[54] *About the U.S. Opioid Epidemic*, U.S. Dep't of Health & Human Servs. https://www.hhs.gov/opioids/about-the-epidemic/ (last updated Mar. 6, 2018).
[55] *The Health of America*, *supra* note 52.
[56] Nora D. Volkow, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Nat'l Inst. on Drug Abuse (May 14, 2014), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.
[57] *Id*.

campaigns that took place prior to their entry to the marketplace.

115. Those new drugs included, but were not limited to: Defendant Purdue Pharma's MS Contin (introduced 1987) and OxyContin (1995); Defendant Janssen's Duragesic (1990), Nucynta (2008), and Nucynta ER (2011); Defendant Actavis' Kadian (1996)[58] and Norco (1997); Cephalon's Actiq (1998) and Fentora (2006); Defendant Endo's Opana and Opana ER (2006); and Defendant Insys' Subsys (2012).

116. Opioids vary by duration. Long-acting opioids, such as Defendant Purdue Pharma's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Defendant 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 Defendant Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

117. Recognizing the enormous financial possibilities associated with expanding the opioid market, the brand name drug Manufacturer Defendants rolled out a massive and concerted campaign to misrepresent the addictive qualities of their product, and to push opioids as safe, effective drugs for the treatment of chronic pain associated with common conditions such back pain, arthritis, headaches and the like. These Manufacturer Defendants promoted the idea that pain should be treated by taking long- acting opioids continuously and supplementing them by also taking short-acting, rapid- onset opioids for episodic pain.

118. The brand name drug Manufacturer Defendants' statements were not only unsupported by, or contrary to the scientific evidence, they were also contrary to

[58] Kadian was first approved in 1996. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

pronouncements by and guidance from the FDA and CDC based on that evidence. As described in detail below, Defendants:

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

b. misrepresented that opioids improve function;

c. misrepresented that addiction risk can be managed;

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

e. falsely claimed that withdrawal is simply managed;

f. misrepresented that increased doses pose no significant additional risks; and

g. falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

119. Underlying each of brand name drug Manufacturer Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants' collective effort to hide from the medical and payor community the fact that there exist no adequate and well-controlled studies of opioid use longer than twelve weeks.[59]

120. Some of this false advertising targeted workers in physically demanding jobs, like construction. For example, one of Purdue Pharma's original videos promoting OxyContin for chronic pain featured North Carolina construction worker Johnny Sullivan, who declared that the drug eased his back pain and enabled him to go back to work. Sullivan, however, became addicted to the drug and later died in a car accident after telling his wife he was having trouble staying awake while driving home from a hunting trip. According to his

[59] *See* Letter from Janet Woodcock, *supra* note 3.

wife, Sullivan frequently dozed off as a side effect of the drug.[60]

121. Similarly, on information and belief, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

122. In connection with this scheme, each brand name drug Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain. As just one example, on information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The amount included $8.3 million by Purdue Pharma, $4.9 million by Jannsen, and $1.1 million by Endo.[61]

123. Further, each brand name drug Manufacturer Defendant promoted the use of opioids for chronic pain through sales representatives who visited individual doctors and medical staff in their offices and small group speaker programs. The Manufacturer Defendants devoted massive resources to direct such sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent $168 million on detailing branded opioids to doctors, including $108 million by Purdue Pharma, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Allergan. These expenditures amount to twice as much as Defendants spent on detailing in 2000.

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[60] John Fauber & Ellen Gabler, *What happened to the poster children of OxyContin?*, MILWAUKEE-WISCONSIN J. SENTINEL, Sept. 8, 2012, http://archive.jsonline.com/watchdog/watchdogreports/what-happened-to-the-poster-children-of-oxycontin-r65r0lo-169056206.html/.

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

124. The deceptive marketing schemes also included, among others, (a) the hiring of certain physicians, "hired guns," to pollute the marketplace with false information regarding the efficacy and risks of opioids for chronic pain treatment; (b) false or misleading materials, speaker programs, webinars, and brochures by purportedly neutral third parties that were really designed and distributed by the Manufacturer Defendants; (c) false or misleading direct, branded advertisements and marketing materials; and (d) the misuse of treatment guidelines.

125. The Manufacturer Defendants' misinformation campaign was intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy. Particularly because of barriers to prescribing opioids associated with their regulation as controlled substances, the Manufacturer Defendants knew doctors would not treat patients with common chronic pain complaints with opioids, and insurers and other third-party payors would not cover such treatment, unless they were persuaded that opioids had real benefits and minimal risks. Accordingly, the Manufacturer Defendants did not disclose to prescribers, patients, third-party payors, or the public that evidence in support of their promotional claims was inconclusive, non-existent, or unavailable. Rather, each Manufacturer Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence.

126. Across the country, demand for prescription opioids exploded. Doctors and medical professionals, swayed by the brand name drug the Manufacturer Defendants' sophisticated propaganda machine, began prescribing opioids for ailment ranging from headaches to neck pain to fibromyalgia. Insurers and third-party payors, likewise misled, paid for or otherwise reimbursed their insureds for such drugs. That unleashed a wave of addiction —

increasing the demand for opioids yet further. Manufacturer Defendants' profits soared.

i. Manufacturer Defendants' Misrepresentation and Corruption of the Scientific Evidence

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

128. There are no controlled studies of the use of opioids beyond sixteen weeks, and no evidence that opioids improve patients' pain and function long-term. For example, two 2007 systematic reviews of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long- term use.[62]

129. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids, as a class, did not demonstrate improvement in functional outcomes over other non-addicting treatments.[63]

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

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[62] Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, 16 EXP. CLIN. PSYCHOPHARMACOL. 405 (Oct. 2008), *author manuscript available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/pdf/nihms97365.pdf.

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

utilization.

131. While opioids may work acceptably well for a while, when they are used on a long-term basis, function generally declines, as does general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.[64]

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

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

134. Rather than test the safety and efficacy of opioids for long-term use, the Manufacturer Defendants led physicians, patients, and health care payors to believe that such tests had already been done. As set forth herein, brand name drug the Manufacturer 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

[64] *See* A. Rubenstein, *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.

be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long- term opioid use outweighed the risks.

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

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

137. In these materials, the Manufacturer Defendants (or their surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Manufacturer Defendants presented these materials to the medical community as scientific articles or studies, even though the Manufacturer Defendants' materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.

138. The Manufacturer Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Manufacturer Defendants knew that the articles distorted the significance or meaning of the underlying study. Most notably, Defendant Purdue Pharma frequently cited a 1980 item in the well-respected New England Journal of Medicine ("Porter & Jick Letter")[65], in a manner that makes it appear that the item reported the results of a peer reviewed study. It is also cited in at least two continuing

[65] J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980).

medical education programs ("CMEs") sponsored by Endo.[66] The Manufacturer Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter-to-the-editor, not a study, much less a peer-reviewed study. The letter was drafted by Hershel Jick, a doctor at Boston University Medical Center, with the help of a graduate student, Jane Porter. It noted, anecdotally, that a review of "current files" did not indicate high levels of addiction among hospitalized medical patients who received narcotic preparation treatment. In full, the letter reads:

> Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients 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, 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.[67]

139. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor, indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were, for how long. None of these serious limitations were disclosed when Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

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[66] AAPM, *Safe Opioid Prescribing Course*, February 2526, 2012 (sponsored by Purdue Pharma and Endo); *Chronic Pain Management and Opioid Use*, October 11, 2012 (sponsored by Purdue Pharma). Each CME is available for online credit.

[67] *Id.*

140. Dr. Jick has complained that his letter has been distorted and misused – as indeed it has. In an interview with Sam Quinones after the letter was published, stated:

> That particular letter, for me, is very near the bottom of a long list of studies that I've done. It's useful as it stands because there's nothing else like it on hospitalized patients. But if you read it carefully, it does not speak to the level of addiction in outpatients who take these drugs for chronic pain.[68]

141. The New England Journal of Medicine itself has since disavowed the Porter & Jick Letter, stating "[the letter] was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy."[69] "We believe," the journal provided, "that this 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."[70]

142. The second major piece of "evidence" used by the Manufacturer Defendants was a 1986 study by Dr. Russell Portenoy in the medical journal Pain. The study, which had a patient cohort of merely 38 patients, claimed that opioids could be used for long periods of time to treat non-cancer related chronic pain without any risk of addiction. The rationale behind the study was that patients in pain would not become addicted to opioids because their pain drowned out the euphoria associated with opioids. As such, the study concluded that opioids should be freely administered to patients with fibromyalgia, headaches, finicky backs, and a host of other issues. According to Portenoy and his co-author, Dr. Kathleen Foley, "opioid maintenance therapy can be a safe, salutary and more humane alternative … in

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[68] Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUS. INSIDER, Mar. 26, 2016, http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5.
[69] Pamela Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 NEW ENG. J. MED. 2194, 2194–95 (2017).
[70] *Id.*

those patients with intractable non-malignant pain and no history of drug abuse."[71] Portenoy's study also cited Porter and Jick's one-paragraph letter to the New England Journal of Medicine.

143. In the years that have followed, both the Porter & Jick Letter and Dr. Portenoy's 1986 study have been expressly disavowed. Neither actually demonstrates that opioids can be safely prescribed for long-term, chronic pain.

144. In a taped interview in 2011, Dr. Portenoy admitted that the information Manufacturer Defendants were pushing was false. "I gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[72]

145. Dr. Portenoy told a fellow doctor in 2010:

> 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. I would cite 6 to 7 maybe 10 different avenues of thought or evidence, *none of which represents 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 … *Because the primary goal was to de-stigmatize, we often left evidence behind.*
>
> *It was clearly the wrong thing to do* and to the extent that some of the adverse outcomes now are as bad as they have become in terms of endemic occurrences of addiction and unintentional overdose death, it's quite scary to think about how the growth in that prescribing driven by people like me led, in part, to that occurring.[73]

146. Dr. Portenoy has further admitted that "[d]ata about the effectiveness of opioids does not exist," and candidly stated "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[74]

ii. Manufacturer Defendants' Use of Key Opinion Leaders to Promote False Information

[71] Russel K. Portenoy & Kathleen Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25 PAIN 171 (1986).
[72] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts,* WALL ST. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[73] Andrew Kolodyny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w (live interview with Dr. Portenoy) (emphases added).
[74] Catan & Perez, *supra* note 72.

147. The brand name drug Manufacturer Defendants spoke through a small circle of doctors, including Dr. Portenoy, who, upon information and belief, were selected, funded, and elevated by the Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

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

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

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

exercise control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."[75]

151. Pro-opioid doctors are one of the most important avenues that Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants knew that doctors rely heavily and less-critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue Pharma that the Purdue Pharma website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue Pharma and concluded that Purdue Pharma's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.[76]

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

153. Dr. Portenoy, whose 1986 article was referenced above, is one example of a KOL whom Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy went on to serve as one of the pharmaceutical industry's most vocal advocates, regularly appearing at conferences and gatherings of medical professionals to promote

[75] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 MORBIDITY & MORTALITY WKLY. REP. 1, 2 (Mar. 18, 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf (hereinafter "*2016 CDC Guidelines*").
[76] *See In re Purdue Pharma L.P.*, Assurance No. 15-151, at ¶ 18 (N.Y. Att. Gen. Aug. 19, 2015), http://www.ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf ("[T]he website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost $231,000, for speaker programs, advisory meetings, and travel costs, to 11 of the Advocates whose testimonials appeared on the site.").

the myth that opioids could be liberally prescribed for non-cancer related chronic pain, without any risk of addiction.

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

155. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed:

> Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.[77]

156. Defendants also paid Dr. Lynn Webster, the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah, to promote opioids. Dr. Webster was President of the AAPM in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER.[78] Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue Pharma. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

[77] *Good Morning America*, ABC (Aug. 30, 2010) (television broadcast).
[78] Journal supplements are paid for by drug manufacturers and, although they may be designed to blend into the rest of the journal, are not peer-reviewed and constitute drug company advertising.

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

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

159. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue Pharma titled, *Managing Patients' Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended using risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors across the country.

160. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should not be seen as warnings, but as indications of under-treated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signed of aberrant behavior, increasing the dose "in most cases ... should be the

clinician's first response." Defendant Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[79]

161. Other KOLs like Dr. Portenoy and Dr. Webster would speak at academic conferences to primary care physicians in an effort to destigmatize opioids and encouraged liberal prescription of narcotics for the treatment non-cancer related chronic pain. They claimed that opioid analgesics have no "ceiling dosage" in that prescribing physicians should increase dosages for patients as high as necessary to treat non-cancer related chronic pain. Invariably, the key piece of "data" cited in support of the proposition that opioids could be safely used to treat chronic pain was the Porter & Jick Letter.

iii. Manufacturer Defendants' Misuse of Front Groups and Treatment Guidelines

162. The brand name drug Manufacturer Defendants also funded multiple organizations to advocate for the use of opioids to treat chronic pain, including through the publication of treatment guidelines. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. The names of the organizations suggest neutrality, but they were anything but. They included the AAPM; American Chronic Pain Association ("ACPA"), American Geriatrics Society ("AGS"), American Pain Foundation ("APF"); the American Pain Society ("APS"), American Society of Pain Education ("ASPE"); the Federation of State Medical Boards ("FSMB"); National Pain Foundation ("NPF"); and the Pain Care Forum ("PCF").

163. The most prominent of these "Front Groups" was APF, which received

[79] Fauber & Gabler, *supra* note 60.

more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Defendant Endo alone provided more than half that funding; Defendant Purdue Pharma was next, at $1.7 million.

164. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue Pharma, Cephalon, Endo, and others to avoid using its line of credit.

165. Multiple members on APF's board, who also reviewed its publications, received funding directly or indirectly from the Manufacturer Defendants, including Dr. Portenoy; Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue Pharma); Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue Pharma); and Lisa Weiss (an employee of a public relations firm that worked for both Purdue Pharma and APF).

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

consumers, physicians, patients, and third-party payors.

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

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

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

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

171. The close relationship between APF and the drug company highlighted in

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

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

173. AAPM, with the assistance, prompting, involvement, and funding of the Manufacturer Defendants, issued treatment guidelines and sponsored and hosted CME programs for doctors essential to Defendants' deceptive marketing of chronic opioid therapy.

174. AAPM has 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 in activities and conferences. Manufacturer Defendants Endo, Purdue Pharma, Cephalon, and Actavis were members of the council.

175. AAPM was viewed internally by Endo as industry friendly, with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its corporate events, and distributed its publications. The conferences sponsored by AAPM promoted opioids – thirty-seven out of roughly forty sessions at one conference alone were

opioid-focused.

176. AAPM's presidents have included the same opioid advocates mentioned above, i.e. Drs. Fine, Portenoy, Webster, and Fishman. Dr. Fishman, a past AAPM president, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are ... small and can be managed."[80]

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

178. In 1997, AAPM and APS jointly issues a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain,* which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[81] The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue Pharma. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.[82]

179. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[83] Fourteen of the twenty-one panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received support from Manufacturer Defendants Janssen, Caphalon,

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[80] *The Current State of Pain Management: An Expert Interview with Scott M. Fishman, MD*, Medscape CME & Education (2005), http://www.medscape.org/viewarticle/500829.
[81] *The Use of Opioids for the Treatment of Chronic Pain: A consensus statement from the American Academy of Pain Medicine and the American Pain Society*, 6 J. PAIN 77 (Spring 1997), *available at* http://www.jpain.org/article/S1082-3174(97)80022-0/pdf.
[82] *Id.*
[83] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 J. PAIN 113 (Feb. 2009), *available at* http://www.jpain.org/article/S1526-5900(08)00831-6/pdf.

Endo, and Purdue Pharma. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache and Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members.

180. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated nationwide during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*. The Manufacturer Defendants widely referenced and promoted the AAPM/APS Guidelines without disclosing the acknowledged lack of evidence to support them.

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

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

chronic pain, including as a first prescription option.[84]

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

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

185. Defendants relied on 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

186. Upon information and belief, the Manufacturer Defendants also combined their efforts through the PCF, which began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

[84] *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*, Fed. of State Med. Bds. (May 2, 1998), *available at* http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/model_0.pdf.

187. PCF membership and participating organizations has included the Healthcare Distribution Management Association (now known as the Healthcare Distribution Alliance and referred to throughout as "HDA"), an industry organization of which all Manufacturer and Distributor Defendants and Defendant CVS Health are members, participants, and/or sponsors; drug manufacturers such as Defendants Endo, Purdue Pharma, Johnson & Johnson, Actavis, and Teva; patient advocacy groups, including APF and ACPA; and other like-minded organizations, almost all of which received substantial funding from Manufacturer Defendants.

188. The PCF has been lobbying on behalf of the Manufacturer and Distributor Defendants for more than a decade. And, from 2006 to 2016 the Distributor and the Manufacturer Defendants worked together through the PCF to spend over $740 million lobbying in the nation's capital and in all fifty statehouses on issues including opioid-related measures.

189. Upon information and belief, PCF also developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[85] This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Manufacturer Defendants' marketing efforts. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." The Manufacturer Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic

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

pain.

190. All of these purportedly neutral, industry-funded organizations took aggressive stances to convince doctors and medical professionals that America was suffering from an epidemic of untreated pain — and that opioids were the solution. Their efforts were successful nationwide.

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

192. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it."[86] ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain."[87] ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain"[88] and only when coupled with "continuous adherence monitoring, in well-selected populations, in

[86] Bradley W. Wargo et al., *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 PAIN PHYSICIAN (Special Issue). S1, S5 (July 2012), http://painphysicianjournal.com/2012/july/2012;15;S1-S66.pdf.
[87] *Id.*
[88] Laxmaiah Manchikanti, et al., *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance*, 15 PAIN PHYSICIAN (Special Issue) S67, S97 (2012).

conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[89]

193. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "[r]outine use of opioids for treatment of chronic non-malignant pain conditions," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[90]

194. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the United States Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.[91]

iv. Manufacturer Defendants' False and Misleading Advertisements and Marketing Materials

195. The Manufacturer Defendants have intentionally made false and misleading statements regarding opioids in their advertising and marketing materials disseminated nationwide.

196. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each defendant conducted and continue to conduct advertising campaigns touting the purported benefit of their branded drugs. Several of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain.

197. Second, the Manufacturer Defendants also engaged in deceptive direct-to-physician marketing, promoting the use of opioids for chronic pain through controlled and

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[89] *Id*. at S96.
[90] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids* at 2, 3 (2011), *available at* https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf.
[91] Mgmt. of Opioid Therapy for Chronic Pain Working Grp., *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, DEP'T OF VETERANS AFFS. & DEP'T OF DEF. 4, 5, 14 (May 2010), *available at* https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf.

trained sales representatives ("detailers") who visited individual doctors and medical staff in their offices and small group speaker programs. In 2014 alone, Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue Pharma, $34 million by Janssen, $13 million by Cephalon on, $10 million by Endo, and $2 million by Actavis.

198. Through these means, and likely others still concealed, the Manufacturer Defendants collaborated to spread deceptive messages about the risks and benefits of long-term opioid use in patient education brochures and pamphlets, websites, ads, and other marketing materials.

199. Through these advertisements and marketing materials, the Manufacturer Defendants falsely claimed that the risk of addiction is low, and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. For example:

a. Upon information and belief, Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue Pharma sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft.[92]

c. Endo sponsored a website, *PainKnowledge*, which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo Website, *PainAction.com*, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are

[92] *Treatment Options: A Guide for People Living with Pain*, AM. PAIN FOUND. 1415, *available at* https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited Mar. 26, 2018) (hereinafter "*APF Treatment Options*").

prescribed for them." Endo also distributed an "Informed Consent" document on *PainAction.com* that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem."

e. Upon information and belief, Janssen reviewed and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, *Prescriberesponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."[93]

g. Purdue Pharma sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* — which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]."[94] This publication is still available online.

h. Upon information and belief, Purdue Pharma also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

200. Through these advertisements and marketing materials, the Manufacturer Defendants also falsely claimed that signs of addiction should not be seen as warnings but are actually signs of undertreated pain ("pseudoaddiction)" that should be treated by prescribing more opioids. For example:

a. Cephalon and Purdue Pharma sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than

[93] Keith Candiotti, *Use of Opioid Analgesics in Pain Management*, PRESCRIBE RESPONSIBLY, http://www.prescriberesponsibly.com/articles/opioid-pain-management.

[94] *A Policymaker's Guide to Understanding Pain & Its Management*, AM. PAIN FOUND. 5, 40 (Oct. 2011), *available at* http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (hereinafter "*APF Policymaker's Guide*").

true addiction.[95] The 2012 edition of *Responsible Opioid Prescribing* remains for sale online.

b. On information and belief, Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated. . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue Pharma published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug- seeking behaviors] in patients who have pain that has not been effectively treated."

e. Upon information and belief, Purdue Pharma sponsored a CME program titled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long acting opioid.

f. Upon information and belief, Purdue Pharma published a pamphlet answering concerns about OxyContin's addictiveness by claiming "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."

201. The 2016 CDC Guidelines reject the concept of pseudoaddiction. The Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a

[95] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

clear benefit."[96]

202. Through these advertisements and marketing materials, Manufacturer Defendants also falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. For example:

a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction."

b. Cephalon and Purdue Pharma sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need[]" a "larger dose" of an opioid, regardless of the dose currently prescribed.[97] The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[98] This guide is still available online.

c. Endo sponsored a website, *PainKnowledge*, which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by an opioid advocate entitled *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?" and the response is, "The dose can be increased. . . .You won't 'run out' of pain relief."[99]

e. Janssen, upon information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Upon information and belief, Purdue Pharma's *In the Face of Pain* website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

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[96] *2016 CDC Guidelines*, *supra* note 75, at 13, 25.
[97] *APF Treatment Options*, *supra* note 92, at 14.
[98] *Id.* at 12.
[99] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, ENDO PHARM. (2004), *available at* http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

g. Purdue Pharma sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages.[100] This publication is still available online.

h. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and others argued to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[101]

203. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[102]

204. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients nationwide would look to opioids first for the treatment of chronic pain. The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. In 2007, for example, Purdue Pharma sponsored a CME entitled Overview of Management Options that was available for CME credit and available until at least 2012. It taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.[103]

205. The Manufacturer Defendants also falsely (1) claimed that there were addiction risk screening tools – such as patient contracts, urine drug screens, and other similar strategies – that allowed them to reliably identify and safely prescribe opioids to patients predisposed to addiction; (2) claimed that opioid dependence and withdrawal are easily managed; (3) described their opioid products as "steady state" — falsely implying that these

[100] *APF Policymaker's Guide*, *supra* note 94, at 32.
[101] Brief of Am. Pain Found., Nat'l Pain Found. & Nat'l Found. for the Treatment of Pain, *United States v. Hurowitz*, No. 05-4474 at 9 (4th Cir. Sept. 8, 2005).
[102] *2016 CDC Guidelines*, *supra* note 75, at 2324.
[103] *See also, e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (April 2007), http://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf (sponsored by Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids).

products are less likely to produce the high and lows that fuel addiction — or as less likely to be abused or result in addiction; (4) stated that patients would not experience withdrawal if they stopped using their opioid products; (5) stated that abuse-deterrent formulations are tamper- or crush-resistant and harder to abuse or misuse; and (6) touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

206. The Manufacturer Defendants' also deceptively marketed opioids through unbranded advertising - i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third-parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties, including Front Groups and KOLs, and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. The purpose of unbranded advertising it to avoid regulatory scrutiny and give the false appearance that deceptive messages came from an independent and objective source.

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

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

100. Certain of the Manufacturer Defendants' detailers have been charged and/or reprimanded for their deceptive promotions. In 2007, Purdue Pharma settled criminal and civil charges against it for misbranding OxyContin. Purdue Pharma was forced to admit it illegally marketed and promoted OxyContin by claiming it was less addictive and less subject to abuse than other pain medications. Purdue Pharma agreed to pay nearly $635 million in fines, and three of its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential to be abused. At the time, this was one of the largest settlements with a drug company for marketing misconduct.

208. Actavis was notified by the FDA in 2010 that certain brochures were "false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."[104] The FDA also found that "[t]hese violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."[105]

209. Upon information and belief, on May 11, 2000, the FDA issued an official

[104] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC at 1 (Feb. 18, 2010), *available at* http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.
[105] *Id.*

warning letter to Purdue Pharma L.P. ordering it to cease use of an advertisement because it was found to mislead the public as to aspects of the efficacy and safety of OxyContin. The ad featured a picture of an elderly woman beneath the caption, "Proven Effective in Arthritis Pain." The FDA found, among other things, that the OxyContin advertisement was misleading since the study relied on for the ad, "only demonstrated OxyContin 20 mg given twice daily to be significantly more effective than placebo [as opposed to 10 mg.] . . . your suggestion that any dose of OxyContin can be used in the treatment of moderate to severe osteoarthritis pain is unsubstantiated, and consequently, misleading." In addition, the FDA noted that, "the Warnings section of the PI states that 'Respiratory depression occurs most frequently in elderly or debilitated patients' . . . [that] risk is not presented in your journal ad."

210. Two former CEOs of Defendant Insys have been charged in an indictment along with other former Insys executives and managers, who were initially charged in December 2016. The indictment said that, beginning in 2012, these CEOs and others devised a scheme to pay speaker fees and other bribes to medical practitioners to prescribe Subsys and to defraud insurers into approving payment for it.

211. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were 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 Manufacturer Defendants and their PBM Defendant allies 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 have issued pronouncements based on actual medical evidence that conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations.

212. Notwithstanding their knowledge, to maximize profits, the Manufacturer Defendants continued to advocate in the false and deceptive manners described herein with the goal of increasing opioid use, purposefully ignoring the foreseeable consequences of their activity in terms of addiction, public health, and health care costs throughout the United States.

D. PBM Defendants Ensured that Opioids Were Covered and Flooded the Market

213. PBMs are brokers between payors (representing patients), drug manufacturers, and retailers, and the gatekeepers to the vast majority of opioid prescriptions filled in the United States.

214. PBMs control drug formularies, which set the criteria and terms under which pharmaceutical drugs are reimbursed. Specifically, PBM formularies determine what drugs (a) will be available (or not available) to patients; (b) for what diagnosis, efficacious or otherwise; (c) in what quantities; (d) at what co-pay; (e) what level of authorization will be required; and (f) what beneficial drugs will not be available. PBMs have the power to limit the number of pills available for legitimate and illegitimate consumption. In this way, PBMs control prescription drug utilization overall.

215. Three large PBMs, Caremark, Express Scripts, and OptumRx (all named Defendants here), manage the drug benefits for more than 180 million lives, more than 70% of the PBM market.[106] In 2015, these three companies covered most of the 4 billion retail

[106] *PBMs*, Nat'l Community Pharmacists Ass'n, http://www.ncpanet.org/advocacy/pbm-resources/what-is-a-pbm- (last visited Mar. 25, 2018).

prescriptions that were covered in the United States.[107] Collectively, PBMs made almost $260 billion in 2016.[108] They are key participants and play a crucial role in the administration of prescription drugs.[109]

216. PBM influence is notable especially considering the lack of competition in the PBM space. Market concentration is an important indicator of a company's ability to earn extraordinary returns, and several segments in the United States pharmaceutical distribution system are highly concentrated.[110]

217. With this kind of monopolistic structure, the top three PBMs have almost exclusive control over the dissemination of opioids. In concert with drug manufacturers who give them rebates as an incentive, they choose which drugs will be on a health plan's formulary, thus determining which drugs will be covered.[111] If a health plan does not cover a drug, that drug will not enter the marketplace to be abused.

218. Every PBM Defendants' formulary is influenced by its financial arrangements with drug manufacturers.

219. For example, notwithstanding its express assurance to its customers that it "agrees to act as a fiduciary in good faith, with candor and due diligence in connection with the

[107] Lydia Ramsey and Skye Gould, *A huge pharma middleman just lost its biggest customer — and it shows how drug pricing really works*, BUS. INSIDER, Apr. 25, 2017, http://www.businessinsider.com/express-scripts-esrx-anthem-not-renewing-pbm-2017-4.
[108] John Breslin, *Health care experts call for more transparency into PBMs*, PATIENTDAILY, Dec. 20, 2017, https://patientdaily.com/stories/511298841-health-care-experts-call-for-more-transparency-into-pbms.
[109] *See generally*, *Health Policy Brief, Prescription Drug Pricing #12: Pharmacy Benefit Managers*, HEALTH AFFS., Sep. 14, 2017, https://www.healthaffairs.org/do/ 10.1377/hpb20171409.000178/full/ (hereinafter "*Health Policy Brief*").
[110] *See* Neeraj Sood, Tiffany Shih, Karen Van Nuys, Dana Goldman, *Follow the Money: The Flow of Funds In the Pharmaceutical Distribution System*, HEALTH AFFS. BLOG, Jun. 13, 2017, https://www.healthaffairs.org/do/10.1377/hblog20170613.060557/full/.
[111] *Health Policy Brief*, *supra* note 109.

performance of [its PBM contract] and any negotiations related thereto,"[112] OptumRx then proceeds to define its formulary as follows:

> A list of prescription drugs administered by PBM that has been evaluated by the PBM for inclusion on its formulary ("***Formulary***"). . . . [T]he drugs included on the PBM's Formulary may be modified by the PBM, with prior approval by [client], from time-to-time as a result of factors including, but not limited to, medical appropriateness, *manufacturer rebate arrangements* and patent expirations.[113]

220. Notably, OptumRx does not explain how "manufacturer rebate arrangements" impact its formulary design.

221. Express Scripts likewise is paid by drug manufacturers based on formulary design:

> Express Scripts contracts for its own account with pharmaceutical manufacturers to obtain rebates attributable to the utilization of certain prescription products by individuals who receive benefits from clients for whom we provide PBM services. *Rebate amounts vary based on the volume of utilization as well as the benefit design and formulary position applicable to utilization of a product*. Express Scripts often pays all or a portion of the rebates it receives to a client based on the client's PBM services agreement. Express Scripts retains the financial benefit of the use of any funds held until payment is made to a client. In connection with our maintenance and operation of the systems and other infrastructure necessary for managing and administering the rebate process, *Express Scripts also receives administrative fees* from pharmaceutical manufacturers participating in the rebate program discussed above. *The services provided to participating manufacturers include making certain drug utilization data available*, as allowed by law, for purposes of verifying and evaluating the rebate payments. The administrative fees paid to Express Scripts by manufacturers for participation in the rebate program do not exceed 3.5% of the [Average Wholesale Price (AWP)] of the rebated products.[114]

222. It is notable that Express Scripts does not commit to share all of the rebates it receives from drug manufacturers with its clients, nor does it commit to share any of

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[112] United Healthcare Servs., Inc. & Emps. Ret. Syst. of Tex., *Pharmacy Benefit Management Services Executed Contract*, Art. 2.3 (2016), https://ers.texas.gov/Doing-Business-with-ERS/PDFs/Contract-for-Pharmacy-Benefit-Management-Services-for-the-HealthSelect-Prescription-Drug-Program.pdf.

[113] *Id*. at Art. 4.1(h)(ii) (second emphasis added).

[114] Express Scripts, Inc. & Oklahoma City Mun. Facility Auth., *Pharmacy Benefit Management Agreement* at 30, Ex. E (2008), http://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage-2.pdf.

the administrative fees. Nor does it explain all of the services for which it receives the administrative fees. Nor does it explain how any of the payments actually influence its formulary design. Also noteworthy is that Express Scripts pegs its administrative fees to AWP, which is a reported price higher than any Express Scripts customer pays for any drug.

223. Express Scripts' standard contract language contemplates that it will derive even further revenue from drug manufacturers in other vaguely described arrangements, none of which are shared with its customers:

> [I]f any, ESI and ESI's wholly-owned subsidiaries derive margin from fees and revenue in one or more of the ways as further described [herein] . . . ESI and ESI's wholly-owned subsidiaries act on their own behalf, and not for the benefit of or as agents for Sponsor, Members or the Plan. *ESI and ESI's wholly-owned subsidiaries retain all proprietary rights and beneficial interest in such fees and revenues* described in the Financial Disclosure and, accordingly, *Sponsor acknowledges that neither it, any Member, nor the Plan, has a right to receive, or possess any beneficial interest in, any such fees or revenues.*[115]

224. A standard Caremark PBM Contract reflects similar perverse incentives. It explains that "'Manufacturer' means a pharmaceutical company that has contracted with Caremark (or its affiliate or agent) *to offer discounts for pharmaceutical products in connection with Caremark's Formulary Services.*"[116]

225. And, "Manufacturer Payments" include revenues received by Caremark,

> from each of the following sources: 1) payments received in accordance with agreements with pharmaceutical manufacturers for formulary placement and, if applicable, drug utilization; 2) rebates, regardless of how categorized; 3) market share incentives; 4) commissions; 5) any fees receives from the sale of utilization data to a pharmaceutical manufacturer; 6) educational grants; 7) administrative management fees; and 8) all compensation from manufacturers including rebates paid by a manufacturer as a result of product inflation caps and/or guarantees negotiated by the Service Provider.[117]

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[115] *Id*. at 89, Sec. 6.4. (emphasis added).
[116] CaremarkPCS Health, L.P. & Nat'l Ass'n of Cntys., *Managed Pharmacy Benefit Service Agreement* at 10, § 10(f) (2006), http://www.nassauclerk.com/agendaindex/Ordinances/other/CS-08-125.pdf (emphasis added).
[117] CaremarkPCS Health, L.L.C. and Fl. Dep't of Mgmt. Servs., *Pharmacy Benefit Management* Services, at 7, § 1.1 (2015), https://www.dms.myflorida.com/content/download/107930/607791/.

226. Caremark's standard PBM contract further explains: "that, in lieu of billing Member County a 'per Claim' fee for Services, Caremark shall retain 100% of the Rebates as reasonable compensation for the Services. Customer and Member County understand and agree that neither they nor any Participant will share in the Rebate monies collected from Manufacturers by Caremark."[118]

227. Caremark also explains that it will encourage the use of its "Preferred Drugs" (those where it has the most lucrative arrangement with a drug manufacturer) over "non-Preferred" drugs. Its standard contract language states that Caremark will encourage the use of "Preferred Drugs" by:

> (i) identifying appropriate opportunities for converting a prescription from a non-Preferred Drug to a Preferred Drug, and (ii) contacting the Participant and the prescriber to request that a prescription be changed to the Preferred Drug. A Preferred Drug is one on the Performance Drug List, which has been developed by Caremark as a clinically appropriate *and economically advantageous subset of the Caremark Formulary*, as revised by Caremark from time to time.[119]

228. People with chronic pain are thus at the mercy of PBMs. Yet PBMs make it more difficult to get pain medication that is less addictive and easier to get opioids, because opioids are generally cheaper than non-opioid alternatives. According to a study by the New York Times and ProPublica, of 35.7 million people on Medicare prescription drug plans, in the second quarter of 2017 only one-third of them had access to Butrans, a drug that contains a less-risky opioid, buprenorphine. Additionally, every drug plan required prior authorization for patients to get not-addictive lidocaine patches.[120]

229. Even when they were asked to limit accessibility to opioids, PBMs

[118] CaremarkPCS Health, L.P. & Nat'l Ass'n of Cntys., *supra* note 116, at 4, § 2.1.
[119] *Id.* at 3, § 1.11.
[120] Katie Thomas & Charles Ornstein, *Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers*, N.Y. TIMES, Sept. 17, 2017, https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html. .

refused. The seeds of the opioid epidemic were sown with early over prescription of OxyContin. In 2001, Purdue Pharma officials "interrupt[ed]" West Virginia efforts to require prior authorization of OxyContin, limiting coverage of the drug to terminally ill cancer patients, with respect to the state employee health plan. Using the financial quid pro quo it had with the state's PBM, it paid Merck Medco (now Express Scripts) to prevent the plan from limiting access to the drug.[121] And this approach wasn't limited to just this plan:

> The strategy to pay Merck Medco extended to other big pharmacy benefit managers and to many other states, according to a former Purdue Pharma official responsible for ensuring favorable treatment for OxyContin. The payments were in the form of "rebates" paid by Purdue Pharma to the companies. In return, the pharmacy benefit managers agreed to make the drug available without prior authorization and with low copayments.
>
> "That was a national contract," Bernadette Katsur, the former Purdue Pharma official, who negotiated contracts with pharmacy benefit managers, said in an interview. "We would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or whether it has prior authorization. We like to keep prior authorization off of any drug."[122]

230. PBMs are "driving patients to opioids, away from abuse-deterrent form (ADF) and less addictive forms of opiates through formulary and pricing strategies."[123]

231. Not only do PBMs place roadblocks in the way of limiting excessive opioid prescriptions, they also make it more difficult to obtain Abuse Deterrent Formula (ADF) opioids. The Three biggest PBMs cover no more than three of the ten FDA-approved ADF opioids. These pills are more difficult to physically alter (crushing to snort or dissolving to inject) and therefore are less prone to abuse. As a result, 96% of all opioid products prescribed in

[121] David Armstrong, *Drug maker thwarted plan to limit OxyContin prescriptions at dawn of opioid epidemic*, STATNEWS, Oct. 26, 2016, https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/
[122] *Id.*
[123] Charles L. Bennett, *Do you have pain, cancer, or diabetes? Your PBM may now be your doctor for these illnesses*, COLLABRX, Dec. 27, 2017, http://www.collabrx.com/pain-cancer-diabetes-pbm-may-now-doctor-illnesses/

2015 were non-ADF.[124]

232. The denial of ADF opioids was endorsed by the Institute for Clinical and Economic Review, a private organization funded in part by some of the largest health plans and PBMs, that claimed that ADF opioids provided neither financial or societal benefits, even though they were given data showing that ADF OxyContin could prevent 4,300 cases of abuse and save $300 million in medical costs for $387 million in drug costs over a five-year period.[125] According to one opinion:

> ICER ignored research that demonstrated abuse deterrent Oxy reduced abuse by 20 percent and reduced the average daily dose of OxyContin from 80mg to 60mg. Perhaps even more important, it reduced sharing and selling of the drug for getting high ("diversion") by nearly 90 percent. The diversion of generic painkillers is responsible for as many as 63 percent of fatal prescription drug overdoses. ICER consciously decided to ignore the human cost of this deadly behavior.
>
> What the ICER report ignores entirely is that one of the factors driving abuse and addiction is the inappropriate use of generic opioids for conditions that have non-opioid, on-label options. Fifty-two percent of patients diagnosed with osteoarthritis receive an opioid pain medicine as first-line treatment, as do 43 percent of patients diagnosed with fibromyalgia and 42 percent of patients with diabetic peripheral neuropathy.[126]

233. What is inconceivable is that PBMs, while making it easy to obtain generic highly addictive opioids, make it harder to obtain treatment. The NY Times/ProPublica study found that PBMs have erected more hurdles to approving addiction treatments than for the addictive substances themselves.[127]

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[124] Peter J. Pitts, *Pharmacy benefit managers are driving the opioid epidemic*, SHAKOPEE V. NEWS, Nov. 21, 2017, http://www.swnewsmedia.com/shakopee_valley_news/news/opinion/guest_columns/pharmacy-benefit-managers-are-driving-the-opioid-epidemic/article_2f6be2a1-c7a3-5f8d-9f3e-61d29d25c84b.html.
[125] Robert Goldberg & Peter Pitts, *ICER Perpetuates the Opioid Crisis, Morning Consult*, MORNING CONSULT, May 11, 2017, https://morningconsult.com/opinions/icer-perpetuates-opioid-crisis/.
[126] *Id.*
[127] Thomas & Ornstein, *supra* note 120.

234. The efforts to artificially increase the number of opioids prescriptions, implemented by PBMs, directly and predictably caused a corresponding increase in opioid abuse. 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."[128] Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[129] The PBMs' role in increasing prescriptions played an enormous role in the current opioid epidemic.

235. PBMs have access to all of the prescriptions filled by their members. PBMs also have the capacity to "perform prescription claims reviews using software algorithms to identify prescribers, pharmacies, or patients who may be using opioids unsafely or else potential fraudulently prescribing, dispensing or using opioids. For example, PBMs may perform retrospective analyses to identify members visiting multiple prescribers or pharmacies, exceeding a threshold of morphine milligram equivalent (MME) daily or filling multiple simultaneous controlled substance claims."[130] Yet, upon information and belief, despite this capability, the PBM Defendants continued to authorize coverage for millions of unnecessary and/or inappropriate opioid prescriptions for years.

236. The PBM Defendants are complicit in the overall fraudulent scheme. Drug

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[128] Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, 64 MORBIDITY & MORTALITY WKLY REP. 1378, 1381 (Jan. 1, 2016), *available at* https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

[129] *Id*.

[130] *The Opioid Epidemic: From Evidence to Impact*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH & CLINTON FOUND. (Oct. 2017), https://www.jhsph.edu/events/2017/americas-opioid-epidemic/report/2017-JohnsHopkins-Opioid-digital.pdf; *see also Managing opioid prescribing and use through pharmacy benefit programs*, NAT'L SAFETY COUNCIL (2014), http://www.nsc.org/RxDrugOverdoseDocuments/RxKit/EMP-Managing-Opioid-Prescribing-and-Use-Through-Pharmacy-Benefit-Programs.pdf ("PBMs *should* provide program 'flags' or warnings to alert the dispensing pharmacist to possible opioid over use and abuse" (emphasis added)).

manufacturers compete for PBM formulary placement (preferred placement results in greater utilization and greater profits) and pay PBMs incentives to avoid pre-authorization requirements that would slow down the flow of prescriptions.

237. PBMs require, and receive, incentives from Manufacturer Defendants to keep certain drugs on and off formularies. These incentives include the payment of rebates by Manufacturers Defendants to PBMs based on utilization, bonuses for moving product and hitting volume targets, and the payment of lucrative administrative fees to maximize PBM profits. Much of this activity is not transparent to anyone, including Plaintiffs, who in good faith hire PBMs to manage their benefits.

238. There are steps the PBMs could take. They could make it easier to access other non-addictive forms of pain relief. They could require doctors to start treating pain first with non-opioid pain medications as recommended by the CDC and turn to opioids as a last resort. They could cover alternative, non-medication treatments for pain. They could make addiction treatment more accessible. They could make their pricing more transparent so everyone could see if they were being improperly influenced by manufacturers to make choices for financial, not medical reasons. But they chose not to for their own financial gain.

E. Manufacturer and Distributor Defendants Violated their Requirements to Prevent Diversion and Report Suspicious Orders under the Controlled Substances Act, 21 U.S.C. § 801 et seq.

239. In addition to their common law duties, Manufacturer and Distributor Defendants are subject to the statutory requirements of the CSA[131] and its implementing regulations. Congress passed the CSA in 1970 partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[132]

[131] 21 U.S.C. § 801 et seq.
[132] H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572.

240. The opioid epidemic was further fueled by Defendants' failure to follow the specific mandates in the CSA requiring them to ensure that highly addictive drugs are not diverted to illegal use. The brunt of the opioid epidemic could have and should have been prevented if Defendants had fulfilled their duties set by statute and common law. Defendants, who operate at every level of the opioid supply chain, had an obligation and duty to act. They did not—and the country, including Plaintiffs, paid the price.

241. Recognizing that highly addictive drugs like opioids can be easily abused and diverted to the black market, Congress, in the CSA set forth two relevant controls on such drugs.

242. First, the DEA sets limits on the quantity of Schedule II controlled substances — such as opioids — that may be produced in the United States in any given year.[133] The DEA determines these quotas based on a variety of data including sales, production, inventories, and exports. The DEA can and does lower quotas as a means of addressing abuse and diversion.

243. Second, Congress anticipated that highly addictive prescription drugs like opioids could be abused and diverted to the black market. The CSA thus sought to combat diversion of prescription narcotics by providing for a closed system of drug distribution in which manufacturers, wholesalers/distributors and retail pharmacies must register with the DEA.

244. Thus, it is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

245. Every registrant is charged with being vigilant in deciding whether a customer, be it a pharmacy, wholesaler, or end customer, can be trusted to deliver or use

[133] *See* 21 U.S.C. § 826(a), 28 C.F.R. § 0.100.

controlled prescription narcotics only for lawful purposes.[134] Specifically, drug manufacturers and distributors—are required to maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[135]

246. In particular, the CSA and its implementing regulations require all registrants to (1) report suspicious orders of prescription opioids to the DEA, and (2) perform required due diligence prior to filling any suspicious orders. A "suspicious order" is defined as including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[136]

247. In addition, the Code of Federal Regulations requires all registrants — including Manufacturer and Distributor Defendants — to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[137]

248. Manufacturer and Distributor Defendants knowingly, recklessly, and/or negligently supplied suspicious quantities of prescription opioids to obviously suspicious physicians and pharmacies serving Plaintiffs' insureds, without disclosing suspicious orders as required by regulations and otherwise circumventing their statutory obligations under Federal law.

249. Manufacturer and Distributor Defendants' refusal to report and investigate suspicious orders had far-reaching effects. The DEA is required to annually set production quotas for regulated drugs. In the context of opioids, however, the DEA has cited the difficulty of determining an appropriate production level to ensuring that adequate quantities are available for legitimate medical use. That is because there are no alternative direct measures available to

[134] *Cf.* 21 U.S.C. § 823(e).
[135] *Id*. at § 823(b)(1); *see also id.* at § 823(a)(1).
[136] 21 C.F.R. § 1301.74(b).
[137] *Id.*

establish legitimate medical need. The DEA's difficulty in setting production quotas was compounded by the fact that the Manufacturer and Distributor Defendants failed to report suspicious orders of opioids and failed to maintain effective controls against diversion. Defendants' deliberate failures thus prevented the DEA from realizing the full extent of opioid diversion for years.

250. Defendants could have (and should have) reported and stopped the flow of prescription opioids into the black market. But Manufacturer and Distributor Defendants intentionally, recklessly, and/or negligently failed to investigate, report, and halt suspicious orders. Accordingly, as a direct result of Defendants' misconduct, substantial and dangerous quantities of prescription opioids were illegally diverted to and overprescribed to Plaintiffs' insureds and others.

251. The costs of these over prescriptions and the additional health care costs attendant to opioid dependence, abuse, and addiction caused by drug diversion were borne primarily by third-party payors, including Plaintiffs.

i. Manufacturer Defendants

252. Manufacturer Defendants are required to design and operate a system to detect suspicious orders, and to report such orders to law enforcement.[138] They have not done so.

253. Upon information and belief, Manufacturer Defendants collected, tracked, and monitored extensive data concerning suspicious physicians and pharmacies, obtained from Distributor Defendants who supplied the Manufacturer Defendants with distribution data in exchange for rebates or other consideration. For example, IMS Health (now QuintilesIMS) furnished Purdue Pharma and other Manufacturer Defendants with fine grained information about the prescribing habits of individual doctors and the ordering habits of individual

[138] *See id.*

pharmacies. The Manufacturer Defendants then used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent.

254. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion, but instead they utilized the data to understand which regions and which doctors to target with their sales force.

255. With the knowledge of improper diversion, Manufacturer Defendants could have but failed to report each instance of diversion to the DEA while rolling out marketing campaigns to churn its prescription opioid sales.

256. Indeed, upon information and belief, Manufacturer Defendants withheld from the DEA information about suspicious orders – and induced others to do the same – to obfuscate the extent of the opioid epidemic. Upon information and belief, Manufacturer Defendants knew that if they or the other defendants disclosed suspicious orders, the DEA would become aware that many opioids were being diverted to illegal channels, and would refuse to increase the production quotas for opioids.

257. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[139] Among the allegations resolved by the settlement, the government alleged

[139] *See* Press Release, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations, U.S. Dep't of Just. (Jul. 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

"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."[140] Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[141]

258. Purdue Pharma also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Through its extensive network of sales representatives, Purdue Pharma had and continues to have knowledge of the prescribing practices of thousands of doctors and could identify doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue Pharma has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs.[142] Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue Pharma is legally obligated to do) or cease marketing to them, Purdue Pharma used the list to demonstrate the high rate of diversion of OxyContin — the same OxyContin that Purdue Pharma had promoted as less addictive — in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue

[140] *Id.*
[141] 2017 Mallinckrodt Admin. Mem. of Agreement 3, *available at* https://www.justice.gov/usao-edmi/press-release/file/986026/download.
[142] *See* Scott Glover & Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. TIMES, Aug. 11, 2013, http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811.

Pharma's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue Pharma failed to take action ——even where Purdue Pharma employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue Pharma did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue Pharma's district manager described internally as "an organized drug ring." In doing so, Purdue Pharma protected its own profits at the expense of public health and safety.[143]

259. In 2016, the New York Attorney General found that, between January 1, 2008 and March 7, 2015, Purdue Pharma's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.[144]

260. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a Los Angeles Times article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it."[145] The New York Attorney General's settlement with Purdue Pharma specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue Pharma continues to profit from the prescriptions of such prolific prescribers.

261. Like Purdue Pharma, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the New York Attorney General found that Endo failed to require sales

[143] *See* Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminal and addicts. What the drugmaker knew*, L.A. TIMES, Jul. 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.
[144] *See In re Purdue Pharma L.P.*, *supra* note 76, at ¶ 11.
[145] Glover & Girion, *supra* note 142.

representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list, The New York Attorney General also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.[146].

262. On information and belief, the other Manufacturer Defendants have engaged in similar conduct in violation of their responsibilities to prevent diversion.

263. The Manufacturer Defendants' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiffs' insureds' communities.

ii. Distributor Defendants

264. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Manufacturer Defendants are also legally required of the Distributor Defendants under federal law.

265. All opioid distributors are required to maintain effective controls against opioid diversion. They are required to create and use a system to identify and report to law enforcement any suspicious orders of controlled substances, such as orders of unusually large size, orders that are disproportionate, orders that deviate from a normal pattern, and/or orders of unusual frequency. To comply with these requirements, distributors must know their customers, must conduct due diligence, must report suspicious orders, and must terminate orders if there are

[146] *See In re Endo Health Solutions Inc. & Endo Pharms. Ind.*, Assurance No. 15-228 (N.Y. Att. Gen. Mar. 1, 2016), *available at* https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

indications of diversion.

266. Under the CSA, anyone authorized to handle controlled substances must track shipments their shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from the point of manufacture through distribution to the point of sale. ARCOS accumulates data on distributors' controlled substances and transactions, which are then used to identify diversion. Each person or entity that is registered to distribute controlled substances such as opioids must report each acquisition and distribution transaction to the DEA.[147] Each registrant must also maintain a complete, accurate and current record of each "substance manufactured, received, sold, delivered, exported, or otherwise disposed of."[148]

267. Each registrant must also comply with the security requirements to prevent diversion set forth in 21 C.F.R. § 1301.71.

268. The DEA has provided guidance to distributors on how to combat opioid diversion. Upon information and belief, since 2006 the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities. Upon information and belief, the DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. Upon information and belief, the DEA has also hosted conferences for opioid distributors and has participated in numerous meetings and events with trade associations.

269. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious

[147] *See* 21 U.S.C. § 827(d)(1); 21 C.F.R. § 1304.33.
[148] 21 U.S.C. § 827(a)(3).

order monitoring and the responsibilities and obligations of registrants to prevent diversion.

270. As part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of each and every order prior to filling. Circumstances that could be indicative of diversion include ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; ordering a disproportionate amount of controlled substances versus non-controlled prescription drugs; ordering excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors.

271. Reporting an order as suspicious will not absolve a distributor of responsibility if the distributor knew, or should have known, that the prescription opioids were being diverted. Indeed, reporting a suspicious order, then filling said order with knowledge it may be suspicious constitutes a failure to maintain effective controls against diversion under 21 U.S.C. §§ 823 and 824.

272. Upon information and belief, the Distributor Defendants' own industry group, the HDA, published Industry Compliance Guidelines titled *Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* emphasizing the critical role of each member of the supply chain in distributing controlled substances. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

273. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements

assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

274. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

275. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.[149] The DEA has repeatedly taken action to attempt to force compliance, including 178 registrant actions between 2008 and 2012, 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions involving immediate suspension orders.[150] The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

a. Upon information and belief, in May 2008, Defendant McKesson agreed to pay $13.3 million to settle the allegations that it failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just sixteen orders as suspicious, all from a single consumer. Moreover, documents that have been recently unsealed show that five months after the 2008 settlement, the McKesson board's audit committee was notified of "serious deficiencies" in its system to spot suspicious opioid shipments.

b. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that 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

[149] Scott Higham & Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.6ec011a1a1db; Lenny Bernstein et al., *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* WASH. POST, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.3076e67a1a28.

[150] Eval. & Inspections Div., Off. of the Inspector Gen., U.S. Dep't of Just., *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), *available at* https://oig.justice.gov/reports/2014/e1403.pdf.

in the DEA Letters."[151] McKesson was fined $150,000,000.[152]

c. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center in Florida amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.[153]

d. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion.

e. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

f. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion.

g. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion.

h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states.

j. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

k. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the CSA.[154] Upon information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable

[151] 2017 McKesson Admin. Mem. of Agreement I.2, *available at* https://www.justice.gov/opa/press-release/file/928476/download.
[152] *Id*. at II.1.j.
[153] *AmerisourceBergen Plant license pulled*, BOSTON GLOBE, Apr. 25, 2007, http://archive.boston.com/news/education/higher/articles/2007/04/25/amerisourcebergen_plant_license_pulled.
[154] Press Release, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act, U.S. Dep't of Just. (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

pharmacies were receiving approximately 69,000 doses/year.

276. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

277. Once the DEA started to enforce suspensions of registrations to distribute controlled substances, rather than comply, manufacturers and defendants spent at least $102 million to undermine the DEA's ability to do so.

278. PCF and the HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. These entities contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. The HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016, and PCF and its members likewise spent significant funds on lobbying efforts.

279. On February 18, 2014, acting at the behest of industry lobbyists including the PCF and HDA, Representative Tom Marino introduced the "Ensuring Patient Access and Effective Drug Enforcement Act" as a supposed effort to define "imminent danger" in the 1970 act.[155]

280. The final, enacted version of this bill required that the DEA show the company's actions had shown "substantial likelihood of an immediate threat," whether in death, serious bodily harm or drug abuse before a suspension order can be sought.[156] It also gave drug companies the ability to submit "corrective action plan[s]" before any penalties could be

[155] H.R. 4069, 113th Cong. (2014), *available at* https://www.gpo.gov/fdsys/pkg/BILLS-113hr4069ih/pdf/BILLS-113hr4069ih.pdf.
[156] S. 483, 114th Cong. § 2(a)(1) (2016) (amending 21 U.S.C. § 823), *available at* https://www.gpo.gov/fdsys/pkg/BILLS-114s483enr/pdf/BILLS-114s483enr.pdf

issued.[157] A DEA memo noted that this bill would essentially destroy the agency's power to file an immediate suspension order of any suspicious drug shipments. The law essentially makes it impossible for the DEA to halt any suspicious narcotic shipments before opioids are diverted to the illegal black market. It also significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.

281. The Distributor Defendants' failure to prevent opioid diversion created an enormous black market for prescription opioids, which market extended to the communities in which Plaintiffs' insureds' live and work. Each Distributor Defendant knew or should have known that the opioids reaching these communities were not being consumed for medical purposes and that the amount of opioids flowing to these communities was far in excess of what could be consumed for medically necessary purposes.

282. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

283. To facilitate compliance with applicable statutes, regulations, professional

[157] *Id*. at § 2(b).

standards, and guidance from government agencies, Distributor Defendants could also have made a number of structural reforms that have been advocated by unions and other investors. These include:

a. Establishing independent board chairs, who have not previously served in management and who has no business or employment ties to the company, to ensure that decisions are made in the best long-term interests of shareholders, including public and labor funds, and the company;

b. Creating special committees of independent directors to investigate and report to investors on how the company boards are assessing and managing legal, financial, and reputational risks related to their opioid business;

c. Establishing misconduct-related clawback provisions to (i) recover incentive compensation in the event of a violation of a company policy relating to non□compliance with a law or regulation that causes significant financial or reputational harm to a company, including supervisory failures, and (ii) require disclosure to shareholders in the proxy statement about such recoveries;

d. Establishing permanent compliance risk committees to provide oversight of the compliance risks associated with opioids and other controlled substances;

e. Strengthening whistleblower protections and establish a zero tolerance policy for any acts of harassment, discrimination or retaliation against employees who report concerns about the company's opioid-related practices or who exercise rights protected under federal or state law; and

f. Developing mechanisms for stakeholder input to management and board members with respect to the opioid epidemic and the communities and other parties affected by the epidemic.

284. The Distributor Defendants made substantial profits over the years based on the diversion of opioids.

285. It was reasonably foreseeable that the Distributor Defendants' conduct in flooding the market with highly addictive opioids would allow opioids to fall into the hands of unintended and unauthorized users.

286. It is reasonably foreseeable that when unintended and unauthorized users

gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death.

287. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic and increase the attendant health care costs faced by Plaintiffs.

288. The Distributor Defendants were aware of widespread prescription opioid abuse but, on information and belief, they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas and in such quantities, and with such frequency that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

289. The use of opioids by Plaintiffs' insureds who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and assistance of the Distributor Defendants. If the Distributor Defendants adhered to effective controls to guard against diversion, Plaintiffs would have avoided significant expense and injury to their members.

290. This threat of injury continues as Distributor Defendants fail to take adequate safeguards to limit the diversion of opioids.

COUNT I
(Federal Civil Rico)

291. Plaintiffs re-alleges and incorporate by reference each of the allegations contained in the preceding paragraphs as if fully set forth herein and further allege as follows:

292. This claim is brought against each Defendant for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961 et seq.

293. Section 1962(c) makes it unlawful "for any person employed by or

associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt."[158]

294. Defendants are persons within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise, the Opioid Abuse Enterprise, through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(b), including acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), § 1512 (tampering with witnesses), § 1952 (use of interstate facilities to conduct unlawful activities), and § 1961(d) ("fraud connected with . . . the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance … as defined in section 102 of the Controlled Substances Act"), in violation of 18 U.S.C. § 1962(c).

295. The term "enterprise" includes "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity."[159] The definition of "enterprise" in Section 1961(4) includes both legitimate and illegitimate enterprises.

296. Specifically, the section "describes two separate categories of associations that come within the purview of the 'enterprise' definition. The first encompasses organizations such as corporations and partnerships, and other 'legal entities.' The second covers 'any union or group of individuals associated in fact although not a legal entity.'"[160] The second category is not a more generalized description of the first.

297. The Opioid Abuse Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants, including their employees and agents; Front

[158] 18 U.S.C. § 1962(c); *United States v. Turkette*, 452 U.S. 576, 580 (1981).
[159] 18 U.S.C. § 1961(4).
[160] *Turkette*, 452 U.S. at 581–82.

Groups, including their employees and agents; and KOLs; as well as external and other as yet unknown marketing firms and distribution agents utilized by Defendants in furtherance of the Opioid Abuse Enterprise. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendants to fraudulently market opioids as scientifically proven as safe and effective for the treatment of chronic pain. The Opioid Abuse Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioid Abuse Enterprise was created and organized to effectuate a pattern of racketeering activity, and maintained systematic links for a common purpose: to increase the use of opioids and fraudulently sell, distribute, and authorize for third-party reimbursement as many opioids as possible by falsely marketing them as safe for treatment of chronic pain, suppressing evidence to the contrary, maintaining their placement on formularies to ensure reimbursement, limiting access to competing less-addictive alternatives, and improperly inducing physicians to prescribe opioids for chronic pain. Each of these entities, including the Defendants, is a "person" distinct from the Opioid Abuse Enterprise.

298. The Opioid Abuse Enterprise described herein engaged in and affected interstate commerce because, *inter alia*, it manufactured, marketed, promoted, sold, distributed, and/or authorized opioids to thousands of individuals and entities throughout the United States.

299. The named Defendants exerted control over the Opioid Abuse Enterprise and management of the affairs of the Opioid Abuse Enterprise.

300. Each of the Defendants either actively participated and/or aided and abetted in the pursuance of this common purpose. Each of the participants in the Opioid Abuse Enterprise described herein received substantial revenue from the scheme, in the form of sales for Manufacturer Defendants, sales and kickbacks for Distributor Defendants who reached particular monthly goals, and rebates or other financial incentives for PBM Defendants who

placed opioids in a preferred place on a formulary or otherwise made opioids available for improper use — all in an effort to maximize profits. Such revenue was exponentially greater than it would have been absent the enterprise. All participants of the Opioid Abuse Enterprise were aware of Defendants' control over the activities of the enterprise. Furthermore, each portion of the enterprise benefited from the existence of the other parts.

301. Under the present facts, each co-conspirator either (a) agreed to operate or manage the enterprise that did and does feloniously deal in controlled substances, an offense punishable under the laws of the United States, or (b) if a co-conspirator did not agree to operate or manage the enterprise, each co-conspirator knowingly agreed to facilitate others who did and do operate or manage the enterprise of felonious dealing in controlled substances, an offense punishable under the laws of the United States.

302. The 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 while benefitting from, encouraging, indirectly creating, contributing to, and maintaining (a) the perception that opioids were safe and effective for the treatment of chronic pain, and (b) an illegal secondary market for highly addictive and dangerous drugs. The predicate acts are not isolated events.

303. While the Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, affairs, offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

304. Defendants deliberately misrepresented the safety and efficacy of opioids and actively concealed and caused others to conceal information about the true safety and

effectiveness of opioids, including by minimizing the addictive qualities of opioids, so that Plaintiffs paid for this drug for chronic pain treatment. By doing so, the Opioid Abuse Enterprise ensured that a larger number of opioid prescriptions for chronic pain would be written, filled, and paid for. This translated into increased revenue (and therefore profits) for Defendants.

305. Additionally, finding it impossible to legally achieve their ever-increasing sales ambitions through legal means, the Defendants systematically and fraudulently violated their statutory duties to maintain effective controls against the diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. Throughout the Defendants' scheme, members of the Opioid Abuse Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market which allowed the Defendants to derive and be unjustly enriched by enormous profits.

306. The Defendants also engaged in lobbying efforts against the DEA's authority to investigate and hold responsible those who failed in their duty to prevent diversion. The Ensuring Patient Access and Effective Drug Enforcement Act was the result of an effort by the Defendants to reduce the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.

307. Defendants' illegal scheme was implemented by an association-in-fact enterprise among the Manufacturer Defendants, the PBM Defendants, and the Distributor Defendants, and executed by each of them. In particular, each of the Defendants was associated with, and conducted or participated in, the affairs of the enterprise, whose purpose was to engage

in the unlawful sales and promotion of opioids, while deceiving the public and federal and state regulators into believing that opioids were safe and effective for the treatment of chronic pain and that Defendants were faithfully fulfilling their obligations under law.

308. The Defendants operated as an association-in-fact enterprise to unlawfully increase the sales of opioids and, in turn, increase and maintain high production quotas, which in turn allowed them to collectively profit from distributing a greater pool of opioids each year and thus unlawfully increase their revenues, and profits. Each member of the association-in-fact enterprise described herein participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding profits generated by the scheme.

309. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

310. At all relevant times, the Opioid Abuse Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.[161]

311. Within the Opioid Abuse Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information with each other and the Front Groups and KOLs on a regular basis. The Defendants used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

312. Each of the Defendants also had a systematic link to each other through

[161] *See Turkette*, 452 U.S. at 580; *Boyle v. United States*, 556 U.S. 938, 944 (2009).

joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities that affected the scheme. The contractual relationships included, on information and belief, rebates and/or chargebacks on opioid sales and security arrangements.

313. For example, the 2012 Meeting Schedule for the PCF is specific example of the Defendants' interpersonal relationships. It demonstrates that the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug manufacturers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

314. Similarly, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," and "networking with HDA wholesale distributor members."

315. After becoming HDA members, the Distributor and Manufacturer Defendants were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Abuse Enterprise efforts, including lobbying and even development of chargebacks. For example,

a. The Industry Relations Council: "composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."[162]

b. The Logistics Operation Committee: "initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain."[163]

[162] *About: Councils and Committees*, HDA, https://www.healthcaredistribution.org/about/councils-and-committees (last visited Mar. 25, 2018).
[163] *Id.*

c. The Manufacturer Government Affairs Advisory 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."[164]

d. The Contracts and Chargebacks 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."[165]

316. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer 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."[166] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[167] The HDA and its conferences were significant opportunities for Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

317. The Manufacturer Defendants also engaged in an industry-wide practice of paying rebates and chargebacks to the Distributor Defendants for sales of prescription opioids. As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturer Defendants paid the

[164] *Id.*
[165] *Id.*
[166] *E.g.*, *Conferences: 2017 Business and Leadership Conference*, HDA, https://www.healthcaredistribution.org/events/2017-business-and-leadership-conference (last visited Mar. 25, 2018).
[167] *Id.*

Distributor Defendants rebates and/or chargebacks on their prescription opioid sales. These contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, shipment notices, and invoices. The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

318. PBM Defendants similarly received rebates and other financial incentives to promote the Manufacturer Defendants' drugs to ensure they were widely sold. The PBM formularies are a critical piece of the enterprise described herein. The enterprise would not have succeeded absent the opioids' placement on the formulary. The formulary controlled which opioids were paid for, reimbursed, and covered by public and private third-party payors, including Plaintiffs.

319. The contractual relationships among the Manufacturer and Distributor Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturers likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Manufacturer and Distributor Defendants as a tool to violate their reporting and anti-diversion duties.

320. Taken together, the interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between three groups

in a tightly knit industry. The Manufacturer, PBM, and Distributor Defendants were not three separate groups operating in isolation or three groups forced to work together in a closed system. The Defendants operated together as a united entity, working together as an ongoing and continuous organization on multiple fronts since at least 2006 if not earlier, to engage in the unlawful sale of prescription opioids.

321. At all relevant times, the Front Groups also were aware of Defendants' conduct, were a knowing and willing participant in that conduct, and reaped benefits from that conduct. Each Front Groups also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of third-party payors including Plaintiffs. But for the Opioid Abuse Enterprise's unlawful fraud, Front Groups would have had the incentive to disclose the deceit by Defendants to their members, constituents, and the public. By failing to disclose this information, Front Groups perpetuated the Opioid Abuse Enterprise's scheme, and reaped substantial benefits.

322. At all relevant times, the KOLs were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying 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 third-party payors, including Plaintiffs. But for the Opioid Abuse Enterprise's unlawful fraud, the KOLs would have been incentivized to disclose the deceit by Defendants to their members, constituents, and the public. By failing to disclose this information, the KOLs

perpetuated the Opioid Abuse Enterprise's scheme, and reaped substantial benefits.

323. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities throughout the United States, many of the Front Groups and KOLs did not challenge Defendants' misrepresentations, terminate their role in the Opioid Abuse Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

324. All participants of the enterprise described herein were aware of Defendants' control over the activities of the enterprise in promoting opioids for use in every situation in which a patient is in pain. Furthermore, each part of the enterprise benefited from the existence of the other parts.

325. The Defendants' racketeering activity was made possible by the Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Abuse Enterprise. The Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires (name what type) in interstate or foreign commerce.

326. The Defendants used, directed the use of, and 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 (a) the safety and efficacy of opioids for the treatment of chronic pain and (b) 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 diversion of opioids into the illicit market.

327. The Defendants' predicate acts of racketeering under 18 U.S.C. § 1961(1)

include, but are not limited to:

a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and 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, omissions and the operation of the PBM formularies.

b. Wire Fraud: The 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, omissions and the operation of the PBM formularies.

328. The Defendants' use of the mail and wires includes, but is not limited to:

a. Representations that they would comply with their duty to (1) design and operate a system to disclose to the registrant suspicious orders of controlled substances, and (2) disclose the results of such a program to resolve concerns about over prescription and diversion of opioids;

b. Communications with and among the enterprise participants that misrepresented the safety and risks of opioid drugs amongst themselves and others;

c. Communications with Plaintiffs, inducing payments for opioids by misrepresenting the safety and risks of opioids;

d. Receiving the proceeds in the course of and resulting from Defendants' improper scheme;

e. Transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the Opioid Abuse Enterprise;

f. Suppressed and destroyed records of suspicious orders to hide evidence of over prescription and diversion;

g. Negotiations concerning opioid formulary placement, opioid alternatives, prior authorization requirements, rebates and other incentives and arrangements between Manufacturer Defendants and PBM Defendants; and

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices,

shipping records, reports, and correspondence, and the prescription opioids themselves.

329. The 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, promoting, and distributing prescription opioids.

330. Many of the precise dates of the Defendants' criminal actions have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Abuse Enterprise alleged herein depended upon secrecy and, towards that end, Defendants took deliberate steps to conceal their wrongdoing. However, given the massive scope of the illegal and scheme, Defendants likely committed thousands, if not millions, of predicate acts of racketeering activity.

331. The multiple acts of racketeering activity that the Defendants committed, or aided and abetted in the commission of, were related to each other, had a similar purpose, involved the same or similar participants and methods of commission, and have similar results affecting similar victims, including Plaintiffs. These acts pose a threat of continued racketeering activity and constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

332. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). 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 the 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 Defendants.

333. These acts were conducted pursuant to an understanding and agreement, whether explicit or implicit, that each member would participate to facilitate and further the purpose of the Defendants' enterprise, which was to maximize profits by manufacturing, distributing, and selling as many opioid pills as possible. Indeed, for the Defendants' fraudulent scheme to work, each Defendant had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

334. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiffs were left with substantial injury to their business and property through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Abuse Enterprise and in furtherance of its fraudulent scheme. But for the conduct of the enterprise's affairs, Plaintiffs would not have sustained damages.

335. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

336. The pattern of racketeering activity is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

337. The 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.

338. At all times during the fraudulent scheme, Defendants had a legal and ethical obligation of candor to and honest dealing with public, the medical community, and third-party payors, like Plaintiffs.

339. As a direct result of the Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while the Plaintiff funds suffered injury caused by the reasonably foreseeable consequences of the over prescription of opioids and health care costs of the opioid epidemic. As explained in detail above, the Defendants' misconduct violated 18 U.S.C. § 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

340. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' injuries in its business and property because Plaintiffs paid for unnecessary and inappropriate opioid prescriptions to treat chronic pain and the health services and expenditures associated with the opioid epidemic.

341. Plaintiffs directly relied on the racketeering activities of the Defendants and the Opioid Abuse Enterprise. Plaintiffs, both directly and indirectly, relied on the representations as to the efficacy and safety of opioid drugs for the treatment of chronic pain as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of opioid drugs' efficacy and safety were based, Plaintiffs, as well as other third party payors and members of the medical community and public, were obligated to rely on Defendants' and the Opioid Abuse Enterprise's representations about opioids. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about the use of opioids for chronic pain and ensure that they were authorized for coverage and broadly distributed.

342. Plaintiffs' injuries were proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiffs would not have paid for the unnecessary and inappropriate opioid prescriptions to treat chronic pain and the health services and

expenditures required as a result of dependence on, abuse of, and addiction to opioids.

343. Plaintiffs have injuries that were directly caused by the Defendants' racketeering activities.

344. Plaintiffs were most directly harmed and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.

345. Plaintiffs seek all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit and pre- and post-judgment interest.

346. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in a sum that exceeds the jurisdiction of all lower courts.

COUNT II
(RICO Conspiracy)

347. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

348. At all relevant times, the Defendants were associated with the Opioid Abuse Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Abuse Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(c), among other provisions.[168]

349. Defendants conspired to violate Section 1962(c), as alleged more fully in Count I, by conducting the affairs of the Opioid Abuse Enterprise through a pattern of racketeering activity, as incorporated by reference herein.

[168] 18 U.S.C. § 1962(d).

COUNT III
(Common Law Indemnity)

350. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

351. Indemnity "arises from contract, express or implied, and is a right of a person, who has been compelled to pay what another should pay in full to require complete reimbursement."[169] This right of indemnity is based on the principle that everyone is responsible for his own wrongdoing, and if another person has been compelled to pay the damages which ought to have been paid by the wrongdoer then the entire loss should be shifted to the party who should bear the loss so as to prevent an unjust result at the expense of the who is free from fault.

352. Plaintiffs have incurred losses, costs, and expenses as a result of having covered the health care costs of unnecessary and inappropriate opioids prescribed for the treatment of chronic pain, and the health care costs resulting from their insureds' dependence on, abuse of, and addiction to opioids. These costs are directly attributable to Defendants' unlawful conduct described herein. Plaintiffs would not have been liable to pay these costs absent Defendants' unlawful conduct.

353. Plaintiffs will continue to incur losses, costs, and expenses as a result of having to cover the health care costs of their insureds directly related to the opioids manufactured, marketed, promoted, sold, distributed, and/or authorized for reimbursement by Defendants herein.

354. By virtue of having unlawfully manufactured, marketed, promoted, sold, distributed, and/or authorized for reimbursement opioids and caused damage and harm to Plaintiffs, Defendants are required by common law to indemnify Plaintiffs for the costs of

[169] *Travelers Indemnity Co. v. Trowbridge*, 41 Ohio St. 2d 11, 1314 (Ohio 1975).

unnecessary and inappropriate opioids prescribed for the treatment of chronic pain, and other health care costs of their insureds directly related to the opioids manufactured, marketed, promoted, sold, distributed, and/or authorized for reimbursement by Defendants herein.

355. Defendants have failed to exonerate, indemnify, and keep indemnified the Plaintiffs for the losses, costs, and expenses incurred, and to be incurred, by Plaintiffs for the costs of unnecessary and inappropriate opioids prescribed for the treatment of chronic pain, and other health care costs of their insureds directly related to the opioids manufactured, marketed, promoted, sold, distributed, and/or authorized for reimbursement by Defendants herein. The Defendants' failure to exonerate, indemnify, and keep indemnified Plaintiffs constitutes a breach of Defendants obligation to indemnify the Plaintiffs.

356. As a consequence of the Defendants' breach of their responsibility to indemnify the Plaintiffs, Plaintiffs have has suffered damages and will continue to suffer damages.

COUNT IV
(Request for Equitable and Injunctive Relief)

357. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

358. Plaintiffs are at risk of continued economic injury, and Plaintiffs' members and families remain at risk of future severe injury and death, due to the actions of Defendants as described above, and are entitled to the following equitable relief:

a. Establishing a research fund to conduct research and study methods to prevent or treat addiction, and other physical and mental harms of opioid abuse and dependence;

b. Establishing an abatement fund to cover the costs of opioid overdose and addiction treatment;

c. Requiring Defendants to establish independent board chairs, who have not previously served in management and who has no business or employment ties to the company, to ensure that decisions are made in the best long-term interests of shareholders, including public and labor funds, and the company;

d. Requiring Defendants to create special committees of independent directors to investigate and report to investors on how the company boards are assessing and managing legal, financial, and reputational risks related to their opioid business;

e. Requiring Defendants to establish misconduct-related clawback provisions to (a) recover incentive compensation in the event of a violation of a company policy relating to non□compliance with a law or regulation that causes significant financial or reputational harm to a company, including supervisory failures, and (b) require disclosure to shareholders in the proxy statement about such recoveries;

f. Requiring Defendants to establish permanent compliance risk committees to provide oversight of the compliance risks associated with opioids and other controlled substances;

g. Requiring Defendants to strengthen whistleblower protections and establish a zero-tolerance policy for any acts of harassment, discrimination or retaliation against employees who report concerns about the company's opioid-related practices or who exercise rights protected under federal or state law; and

h. Requiring Defendants to develop mechanisms for stakeholder input to management and board members with respect to the opioid epidemic and the communities and other parties affected by the epidemic.

i. Requiring Defendants to consider the sale and development of alternative methods of pain management that avoid opioid addiction and the deleterious consequences of opioid use and/or addiction.

COUNT V
(Unjust Enrichment)

359. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

360. As an intended result of their intentional wrongful conduct as set forth in this Complaint, Defendants have profited and benefited from opioid purchases paid for or reimbursed by Plaintiffs.

361. Defendants were aware they were receiving this benefit.

362. Defendants' conduct was designed to bring about this benefit.

363. Defendants have been unjustly enriched in the form of profits because of their wrongful conduct.

364. As a matter of equity, Defendants should be required to disgorge their unjustly obtained profits from the Plaintiffs' payments for or reimbursement of opioids prescribed to their insureds in amounts to be proven at trial.

COUNT VI
(Negligence)

365. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

366. Ohio recognizes that when parties engage in affirmative acts, they must proceed with reasonable care to avoid foreseeable injury. See City of Cincinnati v. Beretta U.S.A. Corp., 95 Ohio St. 3d 416, 421¬22 (2012). Failure to exercise adequate control over manufacturing, marketing, and distribution of dangerous products in ways that foster their illegal sale and results in foreseeable injury is actionable as negligence. *Id.*

367. Defendants, collectively, acted to expand the market for opioids to the treatment

of chronic pain.

368. In doing so, Defendants failed to act with reasonable care in the manufacturing, marketing, promoting, selling, distributing, and/or authorizing for reimbursement of opioids for the treatment of chronic pain.

369. Defendants knew that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain. Defendants knew of widespread prescription opioid addiction and abuse, and diversion to illegal channels. And defendants knew that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed.

370. Nonetheless, Defendants persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids and making opioids readily available to consumers without regard to the likely harm they would cause.

371. Defendants' misinformation campaign was intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

372. Defendants' conduct directly injured Plaintiffs. Defendants' conduct caused Plaintiffs to pay for or otherwise reimburse the cost of millions of unnecessary and/or inappropriate opioid prescriptions, as well as the health care costs associated with opioid addiction and abuse among their insureds, whom Manufacturer Defendants' specifically targeted with their marketing schemes.

373. Defendants knew of or should have known of the foreseeable injuries to Plaintiffs caused by their failure to act with reasonable care. Defendants were aware that their goal of significantly expanding the marketplace for opioids depended in part on comprehensive coverage of opioids by insurers and third-party payors. Defendants knew that their goal of increasing

profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for health care payors, such as Plaintiffs.

374. The aforementioned conduct was a direct breach of the duty Defendants owed to Plaintiff, which was the proximate cause of Plaintiff suffering damages.

COUNT VII
(Common Law Failure to Warn)

375. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

376. Manufacturer Defendants knew that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain.

377. To expand the market for opioids, however, Manufacturer Defendants engaged in a misinformation campaign to alter public perception of opioids, and deceive doctors, federal regulators, and the public about their addictive and unsafe qualities.

378. Because of barriers to prescribing opioids associated with their regulation as controlled substances, Manufacturer Defendants knew doctors would not treat patients with common chronic pain complaints with opioids, and insurers and other third-party payors would not cover such treatment, unless they were persuaded that opioids had real benefits and minimal risks.

379. Accordingly, Manufacturer Defendants spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

380. Manufacturer Defendants did not disclose to prescribers, patients, third-party payors, or the public that evidence in support of their promotional claims was inconclusive, non-existent, or unavailable. Rather, each Manufacturer Defendant disseminated misleading and

unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence.

381. Manufacturer Defendants' misinformation campaign was intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

382. Manufacturer Defendants knew of widespread prescription opioid addiction and abuse, and diversion to illegal channels. Manufacturer Defendants also knew that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed.

383. Manufacturer Defendants further knew that widespread opioid addiction and abuse was harmful to the individuals consuming opioids, their friends, families, and communities, and those, like Plaintiffs, responsible for paying for the health care costs associated with the opioid epidemic.

384. Nonetheless, Manufacturer Defendants unreasonably persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids. In doing so, Manufacturer Defendants failed to take reasonable precautions in presenting opioids to the public.

385. By failing to adequately warn the public, including Plaintiffs, of the dangers of opioids, Manufacturer Defendants' conduct directly injured Plaintiffs. Because of Manufacturer Defendants' misinformation campaign, Plaintiffs paid for or otherwise reimbursed the cost of millions of unnecessary and/or inappropriate opioid prescriptions, as well as the health care costs associated with opioid addiction and abuse among their insureds, whom Manufacturer Defendants' specifically targeted with their marketing schemes.

386. As a consequence of the Manufacture Defendants' breach of their common law

duty to warn, Plaintiffs have suffered damages and will continue to suffer damages.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully ask this Court to award the following relief:

A. For judgment against Defendants, jointly and severally, on all counts herein and an award of all compensatory damages allowed by law, in an amount to be proven at trial;

B. For an injunction and/or other equitable relief to prevent further misconduct and unfair practices by Defendants;

C. For disgorgement of all unjustly obtained profits;

D. For punitive damages;

E. That Defendants and all their directors, officers, employees, agents, servants and all other persons in active concert or in participation with them, be enjoined temporarily during pendency of this action, and permanently thereafter, from acquiring or maintaining, whether directly or indirectly, any interest in or control of any RICO enterprise of persons, or of other individuals associated in fact, who are engaged in, or whose activities do affect, interstate or foreign commerce.

F. That Defendants and all of their directors, officers, employees, agents, servants and all other persons in active concert or in participation with them, be enjoined temporarily during pendency of this action, and permanently thereafter, from committing any more predicate acts in furtherance of the Opioid Abuse Enterprise alleged.

G. That Defendants be required to account for all gains, profits and advantages derived from their several acts of racketeering activity in violation of 18 U.S.C. § 1962(c) as well as from all other violation(s) of applicable federal law(s).

H. That judgment be entered for Plaintiffs and against Defendants for Plaintiffs' actual damages, and for any gains, profits, or advantages attributable to all violations of 18 U.S.C. § 1962(c).

I. That Defendants pay to Plaintiffs treble (triple) damages, under authority of 18 U.S.C. § 1964(c), for any gains, profits, or advantages attributable to all violations of RICO.

J. For attorneys' fees and costs pursuant to any applicable provision of law;

K. For pre- and post-judgment interest as allowed by law; and

L. For any other relief that the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial on all claims in this Complaint.

Dated: April 17, 2018

Respectfully submitted,

/s/ John R. Climaco

John R. Climaco (0011456)
D. Scott Kalish (0063002)
Michael Czack (0034000)
Climaco, Wilcox, Peca & Garofoli Co., PA
55 Public Square
Suite 1950
Cleveland, Ohio 44113
Phone: (216) 621-8484
Fax: (216) 771-1632
jrclim@climacolaw.com
Scottkalishcollc@cs.com
mczack@czacklaw.com

Attorneys for Plaintiffs

Joseph C. Hoffman, Jr., Esq.
George Faulkner, Esq.
Faulkner, Hoffman & Phillips, LLC
20445 Emerald Parkway Drive, Suite 210
Cleveland, OH 44135
(216) 781-3600 Main
(216) 781-8839 Facsimile
hoffman@fhplaw.com

faulkner@fhplaw.com

Attorneys for Plaintiffs Teamsters Local Union No. 52 and 348 Health & Welfare Fund

To be admitted pro hac vice:

Neil L. Henrichsen
Helen H. Albee
Chris Moser
HENRICHSEN SIEGEL, PLLC
301 W Bay Street, Suite 1400
Jacksonville, FL 32202
PH: 904-381-8183
FAX: 904-212-2800
nhenrichsen@hslawyers.com
halbee@hslawyers.com
cmoser@hslawyers.com

Cyrus Mehri
Steven A. Skalet
Jay Angoff
U.W. Clemon
Christine H. Monahan
MEHRI & SKALET
1250 Connecticut Ave, NW, Suite 300
Washington, DC 20036
PH: 202 822-5100
cmehri@findjustice.com
sskalet@findjustice.com
jangoff@findjustice.com
jclemon@findjustice.com
cmonahan@findjustice.com

Wayne Hogan
Leslie Goller
TERRELL HOGAN
233 E Bay Street, Suite80
Jacksonville, FL 32202
PH: 904-722-2228
FAX: 904-632-2027
Hogan@terrellhogan.com
Lgoller@terrellhogan.com

Michael J. Del Giudice
CICCARELLO, DEL GUIDUICE & LaFON
1219 Virginia St. E.-Suite 100
Charleston, WV 25301
PH: 304-343-4440
FAX: 304-343-4464
mikedel@cdlwv.com

Michael Goodstein
HUNSUCKER GOODSTEIN
5335 Wisconsin Ave. N.W.
Suite 410
Washington, DC 20015
PH: 202- 895-5380
mgoodstein@hgnlaw.com