September 11, 2019

ATTORNEY GENERAL RAOUL FILES LAWSUIT AGAINST ADDITIONAL OPIOID MANUFACTURERS AND DISTRIBUTORS

Chicago — Attorney General Kwame Raoul filed a lawsuit against Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; Teva Pharmaceutical Industries Limited; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Allergan Finance, LLC; Actavis Pharma, Inc.; Actavis LLC; Watson Laboratories, Inc.; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation for their roles in the opioid epidemic.

According to Raoul's lawsuit, filed in Cook County Circuit Court, the opioid manufacturers carried out unfair and deceptive marketing campaigns that prioritized profits over public health and resulted in unprecedented levels of opioid prescribing, while the distributors irresponsibly flooded Illinois with opioids, failing in their role as gatekeepers in preventing the diversion of opioids.

"Opioid addiction has destroyed lives and families throughout Illinois," Raoul said. "These opioid manufacturers and distributors selfishly and irresponsibly sacrificed the health and safety of Illinois residents for their own financial gain. Their actions played a key role in the over-prescription, misuse, abuse, and diversion of dangerous opioids that resulted in an opioid crisis. I will continue to investigate and hold accountable all of those responsible for Illinois' opioid epidemic."

Raoul alleged the defendant opioid manufacturers – Johnson & Johnson, Endo, Teva, and Allergan – spent millions of dollars on an unfair and deceptive campaign to shift public perception of opioids, resulting in an increase in opioid prescriptions. According to Raoul, they pushed for the use of more opioids at higher doses and for longer periods of time under the guise of what they characterized as the widespread and problematic under-treatment of pain. The manufacturers also allegedly sought to convince health care providers and patients that opioids were a safe and effective treatment, by minimizing the risk of addiction, touting deceptive concepts like "pseudo addiction," and making false and unsubstantiated claims about the drugs' benefits.

Raoul also alleged the opioid distributors – McKesson, Cardinal, and AmerisourceBergen – contributed to the deadly opioid epidemic by neglecting their responsibility to identify, report and stop suspicious orders. According to Raoul, the distributors flooded Illinois with hundreds of millions of dosage units of opioids with little oversight, fueling the diversion of these drugs towards illegal and harmful uses.

Opioids are often prescribed to treat severe pain, as they reduce the intensity of pain signals reaching the brain; however, they can have serious side effects and are highly addictive. Opioids – such as morphine, hydrocodone, oxycodone, oxymorphone, and methadone – are a class of narcotic drugs that include heroin, some prescription pain relievers, and fentanyl.

According to the Centers for Disease Control (CDC), more than 130 Americans die each day from an opioid overdose. According to the Illinois Department of Public Health (IDPH), more than 2,000 Illinoisans were killed by opioid overdoses in 2017. IDPH's data also shows that between 2011 and 2017, instances of babies born with neonatal abstinence syndrome (NAS), which can occur when a newborn is prenatally exposed to opiates, increased by 64 percent. Babies born with NAS experience a variety of medical complications, including withdrawal symptoms, and often require longer hospital stays after being born.

Raoul's lawsuit seeks to abate and remedy the statewide public nuisance caused by these companies. Raoul also asks the court to prohibit the manufacturers' and distributors' deceptive and unfair conduct in order to ensure it does not happen again in the future, and to hold the companies accountable for the devastation they have caused in Illinois and nationwide.

The lawsuit is part of Attorney General Raoul's ongoing efforts to combat the opioid epidemic and hold accountable companies whose deceptive practices have increased opioid prescriptions at the expense of public health. In April, Raoul's office filed a lawsuit against opioid manufacturer Purdue Pharma for carrying out an aggressive and misleading marketing campaign to increase prescriptions of opioid painkillers as communities throughout Illinois and across the country faced an opioid addiction epidemic. In August, Raoul's office expanded the lawsuit to include several members of the Sackler family, which founded and owns Purdue Pharma, for their roles in directing and approving the company's misleading marketing efforts.

Raoul urges anyone who believes they or a loved one may be addicted to opioids to seek help by calling the Illinois Helpline for Opioids and Other Substances at 833-2FINDHELP, which operates 24 hours a day, seven days a week.

Assistant Chief Deputy Attorney General Thomas Verticchio; Division Chief Susan Ellis; Deputy Bureau Chief Judith Parker; Assistant Attorneys General Lauren Barksi, Jennifer Crespo, Darren Kinkead, Andrea Law, and Vivian Sapthavee are handing the case for Raoul's Consumer Protection Division.

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT – CHANCERY DIVISION

THE PEOPLE OF THE STATE OF ILLINOIS, Plaintiff, v. JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., TEVA PHARMACEUTICAL INDUSTRIES LIMITED, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, WATSON LABORATORIES, INC., MCKESSON CORPORATION, CARDINAL HEALTH, INC., and AMERISOURCEBERGEN DRUG CORPORATION, Defendants.	)	No. 2019CH10481

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

Now comes the Plaintiff, THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, and brings this action against JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., TEVA PHARMACEUTICAL INDUSTRIES LIMITED, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, WATSON LABORATORIES, INC., MCKESSON CORPORATION, CARDINAL

HEALTH, INC., AMERISOURCEBERGEN DRUG CORPORATION, (collectively "Defendants"), for violations of the Illinois Consumer Fraud and Deceptive Business Practices Act ("Consumer Fraud Act"), 815 ILCS 505/1 *et. seq.*, and to abate and remedy the statewide public nuisance created by Defendants, and states as follows:

SUMMARY OF THE CASE

Defendants each played a key role in the opioid crisis— a crisis of over-prescription, misuse, abuse, addiction, and diversion, which has left no state unscathed. While thousands of Americans were dying, Defendants were padding their pockets.

Under the guise of what the Manufacturer Defendants characterized as the widespread and problematic undertreatment of pain, they pushed for the use of more and more opioids at higher doses and for longer periods of time. The Manufacturer Defendants spent millions to shift public perception. They sought to convince healthcare providers and patients that opioids were a safe and effective treatment, by minimizing the risk of addiction, touting deceptive concepts like "pseudoaddiction," and making false and unsubstantiated claims about the drugs' benefits. Their campaign was successful and opioid prescriptions reached new heights. Even in the face of a growing and deadly epidemic, the Manufacturer Defendants continued their unfair and deceptive messaging.

The Distributor Defendants played their part as well, flooding the nation and Illinois with these dangerous and addictive drugs. Shirking their responsibilities to identify, monitor, and report suspicious orders, they shipped millions of drugs into Illinois with little oversight. The Distributor Defendants' misconduct fueled the diversion of these drugs towards illegal and harmful uses.

The opioid crisis continues to devastate communities and families across the country and throughout Illinois. The State brings this lawsuit to compel Defendants to abate the harm resulting from their actions, enjoin ongoing and future misconduct, and hold Defendants accountable for the devastation they have incited in Illinois and nationwide.

PUBLIC INTEREST

1. The Illinois Attorney General believes this action to be in the public interest of the citizens of the State of Illinois and brings this lawsuit pursuant to the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/7(a), and his common law authority to represent the People of the State of Illinois.

JURISDICTION AND VENUE

2. This action is brought for and on behalf of THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, pursuant to the provisions of the Consumer Fraud Act and his common law authority as the Attorney General of the State of Illinois to represent the People of the State of Illinois.

3. Venue for this action properly lies in Cook County, Illinois, pursuant to section 2-101 of the Illinois Code of Civil Procedure, 735 ILCS 5/2-101, in that some of the activities complained of herein out of which this action arose occurred in Cook County.

PARTIES

4. Plaintiff, THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, is charged with enforcement of the Consumer Fraud Act. The Attorney General is also authorized to bring this action pursuant to his common law authority to represent the People of the State of Illinois and *parens patriae* authority to bring an action to abate a public nuisance and vindicate the rights of the public.

A. Manufacturer Defendants

Janssen

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

6. Defendant JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Johnson & Johnson. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc. Johnson & Johnson conducts the pharmaceuticals segment of its business through Janssen Pharmaceuticals, Inc.

7. Defendant ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., formerly known as Janssen Pharmaceutica, Inc. and now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

8. Defendant JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

9. For purposes of this Complaint, any references to the acts and practices of Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively "Janssen") shall mean that such acts and practices are by and through the acts of Janssen's members, owners, directors, employees, salespersons, representatives, and/or other agents.

10. Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. acted together as part of a common enterprise to carry out the conduct alleged in this Complaint.

Endo

11. Defendant ENDO HEALTH SOLUTIONS INC. is a Delaware corporation and is a wholly owned subsidiary of Endo International plc.

12. Defendant ENDO PHARMACEUTICALS INC. is also a Delaware corporation and is a wholly-owned subsidiary of Endo Health Solutions Inc.

13. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. share the same principal place of business in Malvern, Pennsylvania.

14. For purposes of this Complaint, any references to the acts and practices of Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively "Endo") shall mean that such acts and practices are by and through the acts of Endo's members, owners, directors, employees, salespersons, representatives, and/or other agents.

15. Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. acted together as part of a common enterprise to carry out the conduct described in this Complaint.

Teva

16. Defendant TEVA PHARMACEUTICAL INDUSTRIES LIMITED ("Teva Ltd.") is a pharmaceutical company with headquarters in Petah Tikva, Israel. Teva Ltd. operates worldwide, with a significant presence in the United States. Shares of Teva Ltd. are traded on the New York Stock Exchange (symbol: TEVA).

17. Teva Ltd. operates in the United States, including in Illinois, through its North America business segment. North America is Teva Ltd.'s most profitable business segment.

18. Defendant TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly-owned subsidiary of Teva Ltd. Teva USA is registered to do business in Illinois.

19. In August 2016, Teva Ltd. bought Actavis Pharma, Inc. and Actavis LLC from Allergan plc. Thus, since August 2016, Teva Ltd. has owned the generic opioids business that was formerly owned by the Allergan Defendants. As part of this sale and a subsequent settlement agreement, Teva Ltd. assumed the liabilities for the historic conduct of these companies related to generic opioid drugs.

20. Defendant CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Ltd. acquired Cephalon, Inc. in 2011. Cephalon, Inc. is a wholly-owned subsidiary of Teva Ltd.

21. Conduct related to Actiq and Fentora prior to 2011 was carried out by Cephalon, Inc.

22. Since the 2011 acquisition of Cephalon, Inc., Teva Ltd., Teva USA, and Cephalon, Inc. worked together as part of a common enterprise to carry out the conduct alleged in this Complaint. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells Actiq and Fentora through its "specialty medicines" division. The FDA-approved prescribing information and medication guides, which are distributed with Cephalon opioids, disclose that the guides were submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

23. For purposes of this Complaint, any references to the acts and practices of Defendants Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. (collectively referred to herein as "Teva") shall mean that such acts and practices are by and

through the acts of Defendants' members, owners, directors, employees, salespersons, representatives, and/or other agents.

Allergan

24. Defendant ALLERGAN FINANCE, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.) is a Nevada limited liability company that exists for the purpose of holding shares of other companies that manufacture and distribute prescription pharmaceuticals.

25. Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012. The combined company changed its name to Actavis, Inc. in January 2013. In 2016 or 2017, Actavis, Inc. – whose parent company is Allergan plc (f/k/a Actavis plc) – changed its name to Allergan Finance, LLC. Allergan Finance, LLC is a subsidiary of Allergan plc, and is the successor to Actavis, Inc.

26. Allergan Finance, LLC has no employees. Allergan Finance, LLC owns 100% of Allergan, Inc. Allergan, Inc. is the historical Allergan company that was acquired in 2015 by Actavis plc. Allergan Finance, LLC has involvement with opioid products through an indirect relationship of subsidiaries. For example, Norco and Kadian are sold by Allergan USA, Inc. Allergan USA, Inc. is a subsidiary of Allergan, Inc., which is a subsidiary of Allergan Finance, LLC. Allergan Finance, LLC's sole member is Allergan W.C. Holding Inc. f/k/a Actavis W.C. Holding Inc., a Delaware corporation with its principal place of business in Madison, New Jersey.

27. Defendant WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California. Prior to its sale to Teva, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc. n/k/a Allergan Finance, LLC, and was involved in the preparation, manufacture, and sale of Norco.

28. Defendant ACTAVIS PHARMA, INC. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was involved in the sales of Norco and Kadian.

29. Defendant ACTAVIS LLC (f/k/a Actavis Inc.) is a Delaware limited liability company with its principal place of business in New Jersey. Prior to its sale to Teva, Actavis LLC was an indirect subsidiary of Watson Laboratories, Inc., and one of its direct subsidiaries was Actavis Elizabeth, LLC, which is involved in the manufacturing of Kadian.

30. Until August 2016 when they were sold to Teva, Watson Laboratories, Inc., Actavis Pharma, Inc., and Actavis LLC were owned by Allergan plc and were part of the same corporate family as Allergan Finance, LLC, shared many of the same corporate officers and executives, and sold and marketed opioids as part of a coordinated strategy to sell and market the branded and generic opioids of Allergan Finance, LLC, Actavis Pharma, Inc., and Actavis LLC.

31. For purposes of this Complaint, any references to the acts and practices of Defendants Allergan Finance, LLC, Actavis Pharma, Inc., Actavis LLC, and Watson Laboratories, Inc. (collectively "Allergan") shall mean that such acts and practices are by and through the acts of Defendants' members, owners, directors, employees, salespersons, representatives, and/or other agents, except that references to Allergan do not encompass Watson Laboratories, Inc., Actavis Pharma, Inc., and Actavis LLC after the time of their sale to Teva in 2016.

32. Prior to the 2016 Teva sale, Defendants Allergan Finance, LLC, Actavis Pharma, Inc., Actavis LLC, and Watson Laboratories, Inc. acted together as part of a common enterprise to carry out the conduct described in this Complaint.

33. Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Endo Health Solutions Inc., Endo

Pharmaceuticals Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Allergan Finance, LLC, Actavis Pharma, Inc., Actavis LLC, and Watson Laboratories, Inc. are referred to collectively herein as the "Manufacturer Defendants."

B. Distributor Defendants

34. Defendant MCKESSON CORPORATION ("McKesson") is a corporation organized under the laws of Delaware with its principal place of business in San Francisco, California.

35. McKesson is in the business of distributing pharmaceuticals to pharmacies and to institutional providers.

36. Defendant CARDINAL HEALTH, INC. ("Cardinal") is a corporation organized under the laws of Ohio with its principal place of business located in Dublin, Ohio.

37. Cardinal is in the business of distributing pharmaceuticals to pharmacies and to institutional providers.

38. Defendant AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") is a corporation organized and existing under the laws of Delaware with its principal place of business located in Chesterbrook, Pennsylvania.

39. AmerisourceBergen is in the business of distributing pharmaceuticals to pharmacies and to institutional providers.

40. For purposes of this Complaint, any references to the acts and practices of McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Drug Corporation (collectively "Distributor Defendants") shall mean that such acts and practices are by and through the acts of Defendants' members, owners, directors, employees, salespersons, representatives, and/or other agents.

TRADE AND COMMERCE

41. Subsection 1(f) of the Consumer Fraud Act (815 ILCS 505/1(f)), defines "trade" and "commerce" as follows:

> The terms 'trade' and 'commerce' mean the advertising, offering for sale, sale, or distribution of any services and any property, tangible or intangible, real, personal, or mixed, and any other article, commodity, or thing of value wherever situated, and shall include any trade or commerce directly or indirectly affecting the people of this State.

42. At all times relevant hereto, Defendants engaged in trade or commerce in the State of Illinois by marketing, promoting, offering for sale, selling, and/or distributing opioid drugs in Illinois.

The Massive Opioid Public Health Epidemic

43. Opioids are killing people in Illinois and across the United States. Drug overdose is now the leading cause of death for adults under fifty-five.[1] Recent increases in overdose deaths have been so steep that they have contributed to a reduced life expectancy in the United States, something Americans have not seen since World War II.[2]

44. Opioids cause about two thirds of all fatal drug overdoses in this country.[3] From 1999 through 2017, nearly 400,000 Americans died of an opioid overdose, approximately 130 lives lost each day.[4]

45. The opioid crisis is also accelerating. As described below, doctors have prescribed opioids for decades, and the risks related to their use are not new. However, while approximately 8,048 people died of an opioid-related overdose in 1999, 47,600 died of an opioid-related

[1] https://www.nytimes.com/interactive/2018/11/29/upshot/fentanyl-drug-overdose-deaths.html (Last accessed September 3, 2019).
[2] *Id.*
[3] https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w (Last accessed August 27, 2019).
[4] https://www.cdc.gov/drugoverdose/epidemic/index.html (Last accessed August 27, 2019).

overdose in 2017.[5] For the first time in history, Americans are now more likely to die from an opioid overdose than a car crash.[6]

46. The devastating public health consequences of the opioid epidemic extend beyond overdose deaths to addiction, withdrawal, and related concerns. A baby is born about every fifteen minutes in this country suffering from neonatal opioid withdrawal syndrome.[7] In 2014 alone, approximately 32,000 babies were born suffering from this withdrawal syndrome, a more than five-fold increase since 2004.[8] In 2016, the number of new foster care cases involving parents who are using drugs hit the highest point in more than three decades.[9]

47. The opioid crisis did not start by chance or by accident. From 1991 to 2011, the total number of opioid prescriptions dispensed by U.S. pharmacies nearly tripled.[10]Opioid-related deaths increased almost the same amount over the same period.[11] Reported overdose deaths involving prescription opioids also increased almost five times in less than two decades, going from 3,442 in 1999 to 17,029 in 2017.[12] By 2015, almost half of all opioid deaths in the United States involved prescription opioids.[13]

48. The crisis now goes beyond drug dealers and problematic prescribers and into Americans' homes. One report indicates that nearly seventy percent of people who misused

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[5] https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (Last accessed August 27, 2019).
[6]https://www.npr.org/2019/01/14/684695273/report-americans-are-now-more-likely-to-die-of-an-opioid-overdose-than-on-the-ro (Last accessed August 27, 2019).
[7]https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (Last accessed August 27, 2019).
[8] *Id.*
[9] "Opioid crisis straining foster systems as kids pried from homes," Dec. 12, 2017, available at: https://www.nbcnews.com/storyline/americas-heroin-epidemic/opioid-crisis-strains-foster-system-kids-pried-homes-n828831 (Last accessed August 27, 2019).
[10]https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-abuse-heroin-use/increased-drug-availability-associated-increased-use-overdose (Last accessed August 27, 2019).
[11] *Id.*
[12] https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (Last accessed August 27, 2019).
[13] Rose A. Rudd *et al.*, *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*,65 Morbidity and Mortality Weekly Report 1145 (2016).

prescription drugs obtained them from family and friends, including stealing someone else's medication from a home medicine cabinet.[14]

49. The simple act of filling an opioid prescription is itself a significant risk factor for overdose,[15] and opioids can also be deadly even when taken as prescribed.[16] In other words, the opioid epidemic is not a crisis of abuse; it is a crisis of overuse.

50. Prescription opioids have also fueled the illicit market for heroin, which can be cheaper and easier to obtain. A great number of people who inject heroin – in some studies, more than 80 percent – report abusing prescription opioids first, a pattern that is especially high for young people.[17]

51. In addition to the vast human toll opioids have taken on individuals and their families and friends, the epidemic has had drastic consequences for the country's economy. By one estimate, the total costs associated with opioid overdoses, death, and use disorders in this country, including a tremendous loss of productivity in the workforce, exceeded $1 trillion from 2001 to 2017.[18] Hospital costs for the treatment of babies with opioid withdrawal syndrome spiked from approximately $90 million in 2004 to over $560 million in 2014, with over eighty percent of those charges paid by state Medicaid programs.[19]

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[14]https://www.nm.org/about-us/northwestern-medicine-newsroom/press-releases/2018/northwestern-medicine-lurie-and-dea-national-prescription-drug-take-back-day (Last accessed August 27, 2019).

[15] Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016,* 65 Morbidity and Mortality Weekly Report 1, 22-24 (2016) (2016 CDC Guideline).

[16] Letter from Janet Woodcock, MD, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013), available at: https://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf (Last accessed August 27, 2019).

[17]https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use (Last accessed August 27, 2019); Al-Tayyib, PhD, *et al.*, "Prescription opioids prior to injection drug use: comparisons and public health implications," Addict. Behav. 2017 Feb.; 65: 224-28.

[18] https://www.ama-assn.org/delivering-care/opioids/understanding-opioid-epidemic-s-economic-toll (Last accessed August 27, 2019).

[19]https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (Last accessed August 27, 2019).

52. Nevertheless, huge quantities of opioids are still being manufactured and prescribed in this country each year. In 2016, for example, retail pharmacies dispensed 214,881,622 opioid prescriptions.[20] That is enough for about two out of every three Americans to get a bottle of pills.

53. Illinois and its citizens have suffered the effects of the opioid epidemic alongside the rest of the country, and the crisis here has unfortunately mirrored the national trends. Emergency room visits for opioid overdoses rose by 66% between just July 2016 and September 2017.[21] And opioids are now responsible for the vast share – almost eighty percent in 2017 – of all drug overdose deaths in Illinois.[22]

54. Nearly 18,000 people in Illinois died from an opioid overdose between 1999 and 2017.[23] In 2016, opioid-related overdoses claimed the lives of 1,946 Illinoisans. That is more than one and a half times the number of homicides and nearly twice the number of fatal car accidents in the state that year.[24] In 2017, opioid overdoses killed 2,202 people in Illinois, a more than 100% increase compared to 2013.[25]

55. As in the rest of the country, the explosion of the opioid epidemic in Illinois was not random or accidental. The state has been flooded with dangerous drugs. From 2006 to 2014, distributors sent over 3.2 billion dosage units (e.g., pills) of opioids to pharmacies in the state.

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[20] https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html (Last accessed August 27, 2019).

[21] "Illinois emergency rooms see 66 percent spike in opioid overdose visits: report," Chicago Tribune, March 6, 2018, available at: http://www.chicagotribune.com/business/ct-biz-opioid-overdoses-emergency-rooms-0307-story.html (Last accessed August 27, 2019).

[22] *Id.*

[23] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018. Data are from the Multiple Cause of Death Files, 1999-2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program, http://wonder.cdc.gov/mcd-icd10.html (Last accessed August 27, 2019).

[24] State of Illinois Comprehensive Opioid Data Report, Illinois Department of Public Health, December 4, 2017, p. 3 available at: http://www.dph.illinois.gov/sites/default/files/publications/publicationsdoil-opioid-data-report.pdf (Last accessed August 27, 2019).

[25] Illinois Department of Public Health Opioid Data Dashboard, available at: https://idph.illinois.gov/OpioidDataDashboard/ (Last accessed August 29, 2019).

Over 988 million opioid dosage units were sent to Cook County alone during that time period. Hardin County, which according to the 2010 census was the state's least populous county, and has only about 4,320 residents, received over 4.2 million units of the drugs during this period.

56. The total number of opioid prescriptions filled in Illinois increased by 25%, or nearly 2 million prescriptions, from 2008 to 2014.[26] Although there was a modest decline in prescriptions in later years, the totals remained staggeringly high. In 2014, 2015, and 2016, prescribers wrote 62.3, 59.1, and 56.8 prescriptions per 100 persons, respectively.[27] Trends in the overall number of prescriptions written also only capture part of the crisis, as the number of overdose deaths specifically related to prescription opioid drugs more than doubled in Illinois between 2013 and 2016.[28]

57. The epidemic has also significantly affected the Illinois economy. By one estimate, the rise in opioid dependency from 1999 to 2015 led to a reduction in the Illinois work force totaling over 84,000 prime-age workers and a loss of over one billion work hours. That translates into a $69.2 billion loss in economic output and a 60% reduction in GDP growth.[29]

58. Between 2011 and 2016, there was a 53% increase in the neonatal abstinence syndrome (NAS) rate in Illinois.[30] Along with the clear human tragedy, there are substantial economic costs associated with these births. Babies born with NAS may experience a variety of withdrawal symptoms, medical complications, and prolonged hospital stays. In 2015, the median length of

[26] Reichert, Jessica; *et al.*, Opioid Prescribing in Illinois: Examining Prescription Drug Monitoring Program Data, May 23, 2018, at p. 3, available at: http://www.icjia.state.il.us/assets/articles/PMP_Article_050918.pdf (Last accessed August 27, 2019).
[27] Centers for Disease Control and Prevention Surveillance Report of Drug-Related Risks and Outcomes, United States 2017 at p. 41, available at: https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf (Last accessed August 27, 2019).
[28] State of Illinois Comprehensive Opioid Data Report, *supra* note 24, at p. 10.
[29] https://www.americanactionforum.org/project/opioid-state-summary/illinois/ (Last accessed August 27, 2019)
[30] State of Illinois Comprehensive Opioid Data Report, *supra* note 24, at p. 20.

an Illinois hospital stay after birth was 13 days longer for infants with NAS, and median hospital charges for infants with NAS were ten times higher.[31]

59. The State has spent and continues to spend substantial public resources on medical services, law enforcement, prosecution, corrections, worker's compensation, diversion programs, probation, treatment, and child welfare related to opioids. For example:

a. Between Q1 2014 and Q3 2016, statewide hospitalization rates for all opioid overdoses increased 42%, opioid analgesic overdoses increased 45%, and heroin overdoses increased 39%.[32] These numbers continue to rise at alarming rates, with the number of emergency department visits for suspected opioid overdoses increasing by 66% in Illinois between July 2016 and September 2017.[33]

b. Emergency medical service (EMS) providers are often the first responders on the scene of an opioid overdose. Under the Heroin Crisis Act, all EMS vehicles in Illinois must be equipped with naloxone, a drug that can quickly reverse an opioid overdose. 9,272 EMS naloxone administrations were reported to the Illinois Department of Public Health for 2015, a 32.6% increase over 2013. Further, in large part due to the presence of fentanyl and other synthetic opioids in substances being used, the number of EMS runs that required two administrations of naloxone increased by over 50% from 2013-2015, and the number of runs requiring three administrations increased over 75%.[34]

c. 19,289, or nearly 30%, of publicly-funded drug treatment admissions in Illinois in 2015 were for persons who indicated opioids as their primary substance of abuse.[35]

d. In 2016, 2,241 Illinois prisoners indicated opioids as their primary substance of misuse. In 2017, nine Illinois drug and mental health courts reported one-third of their participants had an opioid use related diagnosis.[36]

60. As detailed below, Defendants understood the risks associated with opioids, but chose to market, promote, sell, and/or distribute opioid products in ways that led to substantial increases

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[31] *Id.*

[32] State of Illinois Comprehensive Opioid Data Report, *supra* note 24, at p. 12.

[33] Emergency Department Data Show Rapid Increases in Opioid Overdoses, CDC Press Release, Mar. 6, 2018, available at: https://www.cdc.gov/media/releases/2018/p0306-vs-opioids-overdoses.html (Last accessed August 27, 2019).

[34] State of Illinois, The Opioid Crisis in Illinois Data and the State's Response, at pp. 2-4, available at: http://www.dhs.state.il.us/OneNetLibrary/27896/documents/OpioidCrisisInIllinois_051617.pdf (Last accessed August 27, 2019).

[35] *Id.* at p. 6.

[36] Reichert, *supra* note 26, at p. 3.

in both the quantity and power of the drugs coming into Illinois. They are substantially responsible for this crisis.

The Severe Risks of Opioids Far Outweigh Their Benefits

61. Opioids are central nervous system depressant drugs that attach to receptors in the brain, spinal cord, gastrointestinal tract, and elsewhere in the body and modulate function. Opioids reduce the intensity of pain signals reaching the brain, but they can also have serious side effects, including respiratory depression, and can cause death.

62. Opioids are a class of narcotic drugs that include heroin, certain prescription pain relievers, and synthetically manufactured analogues such as fentanyl. There are several different opioid medications – morphine, hydrocodone, oxycodone, oxymorphone, hydromorphone, tapentadol, buprenorphine, and methadone being the most common.

63. Opioids come in two basic formulations: immediate-release and extended-release. Immediate-release opioids deliver the full dose quickly as the substance dissolves. Extended-release opioids are concentrated forms of immediate-release drugs, but contained in a time-release matrix that is supposed to release the drug over time.

64. The immediate-release opioid market is heavily generic. The extended-release market consists far more of branded products.

65. The Manufacturer Defendants manufactured, marketed and sold both immediate-release and extended-release opioid products.

66. The Distributor Defendants distributed and sold both immediate-release and extended-release opioid products.

Opioids are highly addictive

67. Opioids are extremely addictive and opioid use can result in tolerance, dependence, cravings, and withdrawal symptoms. Studies have found diagnosed addiction rates in primary care settings as high as 26%.[37] Among opioid users who received four prescriptions in a year, 41.3% meet diagnostic criteria for a lifetime opioid-use disorder.[38]

68. A 2017 Center for Disease Control ("CDC") study determined that the probability of long-term opioid use escalates most sharply after five days, and surges again when one month of opioids are prescribed.[39] A patient initially prescribed one month of opioids has a 29.9% chance of still using opioids at one year.[40] In one study, almost 60% of patients who used opioids for 90 days were still using opioids five years later.[41]

69. Patients whose initial prescription was for an extended-release opioid have the highest probabilities of continued use with a 27.3% likelihood of using opioids one year later, and a 20.5% likelihood of using opioids three years later.[42]

70. In 2013, the U.S. Food and Drug Administration ("FDA") observed that extended-release opioids present "disproportionate safety concerns" and that the data show that the risk of misuse and abuse is greater for extended-release opioids.[43]

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[37] Dowell, *supra* note 15, at 22-24.

[38] Joseph A. Boscarino, Stuart N. Hoffman & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates,* 6 Substance Abuse and Rehabilitation 83 (2015); *see also* Joseph A. Boscarino *et al.*, *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria,* 30 Journal of Addictive Diseases 185 (2011) (showing a 34.9% lifetime opioid use disorder).

[39] Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015,* 66 Morbidity and Mortality Weekly Report 265-269 (2017).

[40] *Id.*

[41] Bradley C. Martin *et al.*, *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study,* 26 J. Gen. Internal. Med. 1450 (2011).

[42] Shah, *supra* note 39.

[43] Woodcock Letter (Sept. 10, 2013), *supra* note 16.

71. The risks of addiction and negative side effects or complications increase when opioids are administered long-term.[44] In 2013, the FDA noted that the data show that risk of misuse and abuse is greatest for extended-release opioids and observed that these drugs are often used chronically.[45]

72. One study has shown that the duration of opioid therapy is a strong risk factor for opioid use disorder— a problematic pattern of opioid use leading to clinically significant impairment or distress.[46] In fact, a study published in 2015 found that 1 in 5 patients on long-term opioid treatment will develop opioid use disorder.[47]

73. Opioids are most dangerous when taken long-term and when taken in high doses.

74. Higher doses of opioids are dangerous in a number of ways. A CDC clinical evidence review found that higher opioid dosages were associated with increased risks of motor vehicle injury, opioid use disorder, and overdose, and that the increased risk rises in a dose-dependent manner.[48]

75. Another study found that higher daily doses and possible opioid misuse were also (a) strong predictors of continued use, and (b) associated with increased risk of overdoses, fractures, dependence, and death.[49]

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[44] *See e.g.*, Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies,* 81 Drug and Alcohol Dependence 103, 104 92006) (noting increased risk of addiction for long-term administration of opioids).
[45] Woodcock Letter (Sept. 10, 2013), *supra* note 16.
[46] Mark J. Edlund *et al.*, *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-Cancer Pain,* 30 Clin. J. Pain 557-564 (2014).
[47] Louisa Degenhardt *et al.*, *Agreement between definitions of pharmaceutical opioid use disorders and dependence in people taking opioids for chronic non-cancer pain (POINT): a cohort study,* 2 the Lancet Psychiatry 314-322 (2015).
[48] Dowell, *supra* note 15, at 22-24.
[49] Edlund, *supra* note 46.

76. Accordingly, in 2016 the CDC recommended that physicians carefully reassess increasing opioid doses beyond 50 morphine milligram equivalents (MMEs), and avoid exceeding 90 MMEs/day.[50]

77. For patients taking a daily dose of more than 120 MMEs over a period greater than 90 days, the chance of developing an opioid use disorder increases 122-fold.[51]

78. At high doses, patients are also at higher risk of poor functional status, increased pain sensitivity, and continuation of opioid treatment for a prolonged period.[52]

Opioids are deadly and dangerous

79. The last 20 years have also proven that opioids are deadly. As Dr. Thomas Frieden, the Director of the CDC from 2011 to 2017, explained, "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[53]

80. Overdose risk from opioids begins at very low doses, doubling when the daily dose is between 20 MMEs and 49 MMEs; by 100 MMEs, the risk of death increases 9-fold.[54]

81. In Illinois alone, nearly 18,000 people died from an overdose involving an opioid between 1999 and 2017.[55]

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[50]Dowell, *supra* note 15, at 22-24.
[51]Edlund, *supra* note 46.
[52] Ballantyne JC. *Opioid analgesia: perspectives on right use and utility.* Pain physician 2007; 10:479-91.
[53] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline,* 374 New Eng. J. Med. 1501 (2016).
[54]Dunn, *et al.*, *Overdose and Prescribed Opioids: Associations Among Chronic Non-Cancer Patients*, Ann Intern. Med 152(2): 85 – 92 (January 19, 2010).
[55] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018. Data are from the Multiple Cause of Death Files, 1999-2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program, http://wonder.cdc.gov/mcd-icd10.html (Last accessed September 10, 2019).

82. Overall, 1 in every 550 patients on opioid treatment dies of opioid-related causes a median of 2.6 years after their first opioid prescription. That number increases to 1 in 32 for patients receiving 200 MMEs/day.[56]

83. Aside from overdose, long-term opioid use is associated with a significant increase in mortality from other causes, such as cardiovascular events.[57]

84. Opioids are also associated with numerous other side effects including gastrointestinal problems, delayed recovery from injury, cognitive impacts, endocrine impacts, hyperalgesia (increased sensitivity to pain), increased risk of fractures, gastrointestinal bleeding, hospitalization among the elderly, tolerance (need for increasing dose to maintain effect), dependence (causing withdrawal if stopped), and addiction.[58]

85. Opioids carry special risks for certain vulnerable populations. Neonatal abstinence syndrome (NAS) was first described in the 1970s, identified among neonates whose mothers most commonly used heroin or were on methadone maintenance. NAS refers to the collection of signs and symptoms that occur when a newborn prenatally exposed to opiates experiences opioid withdrawal.[59] The syndrome is primarily characterized by irritability, tremors, feeding problems, vomiting, diarrhea, sweating, and, in some cases, seizures.

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[56]Frieden, *supra* note 53.
[57] Wayne A. Ray *et al.*, *Prescription of Long-Acting Opioids and Mortality in Patients With Chronic Noncancer Pain*, 315 J. Am. Med. Ass'n 2415 (2016).
[58] Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications* (2014), citing Leonard Paulozzi *et al.*, *CDC Grand Rounds Prescription Drug Overdoses – a U.S. Epidemic*, 61 Morbidity and Mortality Weekly Report 10 (2012).
[59] Chasnoff, I, Gardner, S. (2015). Neonatal abstinence syndrome: a policy perspective – Journal of Perinatology (2015) 35: 539-541.

86. National surveillance studies have demonstrated that the incidence of NAS increased from 3.4 per 1,000 hospital births in 2009 to 5.8 per 1,000 births in 2012 – a 70% increase in only three years. Since 2000, there has been a five-fold increase in NAS.[60]

87. Since 2011, the rate of NAS in Illinois has similarly risen. In fact, from 2011 to 2017, there was a 64% statewide increase in the NAS rate in Illinois, according to hospital discharge data for all Illinois hospitals.[61] This problem has been particularly dire in Illinois' rural communities where the incidence of NAS rose by 212% between 2011 and 2015.[62]

88. Opioids also pose risks for children and adolescents. Most of the use in this population is off-label as opioids are not approved for children. Use of prescription opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse.[63] The misuse of opioids in adolescents strongly predicts the later onset of heroin use.[64] Nonetheless, the 2016 CDC Guideline found that there have been significant increases in opioid prescribing for children and adolescents, for conditions such as headaches and sports injuries.

89. Opioids also pose special risks for older patients as well. Older patients on opioids are particularly prone to breathing complications, confusion, drug interaction problems, and an increased risk for falls and fractures.[65]

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[60] Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. (2012). Neonatal abstinence syndrome and associated health care expenditures. Journal of the American Medical Association, 307(18): 1934-1940; Patrick SW, Davis MM, Lehman CU, Cooper WO. (2015). Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States, 2009-2012. Journal of Perinatology, 35(8): 650-655.

[61] Illinois Department of Public Health, Neonatal Abstinence Syndrome Advisory Committee Final Report to the General Assembly, 03/31/2019 at p. 3, available at: http://www.ilga.gov/reports/ReportsSubmitted/379RSGAEmail835RSGAAttachNAS-Annual%20Report%20March%202019.pdf (Last accessed September 9, 2019).

[62] The State of Rural Health in Illinois: Great Challenges and a Path Forward at p. 3, available at: https://www.siumed.edu/sites/default/files/u9451/rhs_stateofillinois_final1115.pdf (Last accessed September 9, 2019).

[63] Dowell, *supra* note 15.

[64] *Id.*

[65] *Resources List Opioid Use in the Older Adult Population*, Issue I Vol. 1 at p. 1, Substance Abuse and Mental Health Services Administration, U.S. DEP'T HEALTH & HUMAN SERVS. (August 2017).

90. In addition, researchers in a 2010 study of older adults, published in the *Archives of Internal Medicine*, found greater risk in "[a]ll-cause mortality after only 30 days for oxycodone and codeine users."[66]

The unproven and transient benefits associated with long-term opioid use do not outweigh the significant risks

91. Not only is it undisputed that opioids carry serious risks of addiction, adverse health outcomes, and death, but any corresponding benefits of opioid treatment, particularly for long-term, chronic pain, are unproven.

92. The CDC published a Guideline for Prescribing Opioids for Chronic Pain in 2016. This guideline, published after a "systematic review of the best available evidence" by an expert panel free of conflicts of interest,[67] determined that no study exists to show opioids are effective for outcomes related to pain, function, and quality of life.[68]

93. Indeed, as Dr. Frieden of the CDC and Dr. Debra Houry, the Director of the National Center for Injury Prevention and Control, explained in 2016: "the science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits."[69]

94. Opioids, when used long-term, cause tolerance, meaning larger and larger doses are necessary to get the same effect.[70] Long-term use also causes dependence, meaning that attempts

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[66] Solomon, Daniel, *et al.*, The Comparative Safety of Opioids for Nonmalignant Pain in Older Adults. Archives of Internal Medicine, 2010, 170(22):1979-1986.
[67] Dowell, *supra* note 15, at 2.
[68] *Id.* at p. 9.
[69] Frieden, *supra* note 53.
[70] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain*, 170 Archives of Internal Med. 1422 (2010).

to stop using the drug cause withdrawal symptoms. In addition, long-term opioid use is associated with hyperalgesia, or heightened sensitivity to pain.[71]

95. While opioids may provide relief in the short term, they fail for their stated purpose of relieving pain and improving function when used long-term. In 2009, Dr. Andrea Rubinstein described a common experience for patients on long-term opioid treatment:

> Opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.[72]

96. The 2016 CDC Guideline notes that "patients who do not experience clinically meaningful pain relief early in treatment (i.e. within 1 month) are unlikely to experience pain relief with longer-term use."[73]

97. A 2006 Danish study found that "it is remarkable that opioid treatment of chronic non-cancer pain does not seem to fulfill any of the key outcome goals: pain relief, improved quality of life and improved functional capacity."[74]

98. Similarly, a 2008 study in the journal *Spine* found that long-term opioid users are more likely to be disabled and unable to work, as well as more likely to be addicted.[75]

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[71] Marion S. Greene & R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2 Current Addiction Reports 310 (2015).
[72] A. Rubinstein, *Are we Making Pain Patients Worse?*, Sonoma Medicine, (Fall 2009).
[73] Dowell, *supra* note 15, at 13.
[74] Jorgen Erickson *et al.*, *Critical Issues on Opioids in Chronic Non-Cancer Pain: Ann Epidemiological Study*, 125 Pain 172, 176-77 (2006).
[75] Jeffrey Dersh *et al.*, *Prescription Opioid Dependence Is Associated With Poorer Outcomes in Disabling Spinal Disorders*, 33 Spine 2219 (2008).

99. A 2012 study in *The Journal of Pain*, which followed 69,000 women over three years, found that patients who received opioid treatment were less likely to have improvement in pain, and had worsened function.[76]

100. In 2012, a group of medical providers petitioned the FDA to impose limits on opioid use. The FDA considered the state of evidence and concluded that it was "not aware of adequate and well-controlled studies of opioid use longer than 12-weeks."[77] The FDA went on to note that more data was needed "on the point at which the risk of opioid use at escalating doses and longer durations of treatment may outweigh the benefits of opioid analgesic therapy."[78]

101. One recent study published by the *Journal of the American Medical Association* found that treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months. The results of the study do not support the initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain.[79]

102. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, owing to greater side effects and slower returns to work.[80] In addition, receiving an opioid for more than seven days increased patients' risk of being on work disability one year later, and an opioid prescription as the first treatment for a workplace injury doubled the average length of the claim.

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[76] Frieden, *supra* note 53, citing Jennifer Brennan Braden *et al.*, *Predictors of Change in Pain and Physical Functioning Among Post-Menopausal Women with Recurrent Pain Conditions in the Women's Health Initiative Observational Cohort,* 13 J. Pain 64 (2012).

[77] Woodcock Letter, (Sept 10, 2013), *supra* note 16.

[78] *Id.*

[79] Erin E. Krebs, MD, MPH, *et al.*, *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain The SPACE Randomized Clinical Trial*, JAMA, 2018, 319(9):872-882.

[80] Gary M. Franklin *et al.*, *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries,* 33 Spine 199 (2008).

103. Despite the tremendous increase in opioid prescriptions from 1999 to 2015, the overall prevalence of patient-reported pain has remained consistent.[81] Thus, the massive expansion of prescribing opioids for pain has made little progress in reducing chronic pain.

Defendants profited handsomely from increased use of opioids

104. The Manufacturer Defendants promoted the expansive use of opioids, despite the lack of evidence of their benefits when used for chronic pain and in spite of their recognized risk, leading to a nationwide epidemic.

105. The Distributor Defendants fueled the epidemic by enabling and allowing the diversion of opioids, despite their obligation to prevent it.

106. The underlying motive for Defendants' misconduct was profit and they found the widespread use of opioids to be exceedingly financially lucrative.

DEFENDANTS' UNFAIR AND DECEPTIVE ACTS AND PRACTICES

A. Manufacturer Defendants

107. The Manufacturer Defendants' public perception campaign prioritized profits over public health, inciting unprecedented levels of opioid prescribing and leading to a devastating and deadly crisis that has reached every corner of the country.

Janssen

108. Janssen has been one of the largest suppliers of opioids and their ingredients in the global pharmaceutical market.

109. Janssen has marketed and sold its opioid products under several brands. These products include Duragesic, Ultram, Ultram ER, Ultracet, Nucynta and Nucynta ER. Janssen also manufactured a generic version of Duragesic.

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[81] Matthew Daubresse *et al.*, *Ambulatory Diagnosis and Treatment of Non-Malignant Pain in the United States*, 2000-2010, 51 Med. Care 870 (2013).

110. At times between 2002 and 2009, Duragesic accounted for at least $1 billion in annual sales, and in 2014 alone, Nucynta and Nucynta ER accounted for $172 million in sales.

111. Janssen has engaged in numerous deceptive and unfair acts and practices designed to push opioids for long-term use at high doses, all to increase its sales of opioids. Janssen did this despite the lack of evidence that opioids improve patients' quality of life and functionality long-term and despite the well-documented risks of its drugs.

Janssen was a top supplier of raw ingredients for other opioid manufacturers

112. Johnson & Johnson played a unique role in expanding the opioids market. From the 1990s through at least 2016, Johnson & Johnson wholly owned two subsidiaries that, together, supplied other opioid manufacturers with opioid active pharmaceutical ingredients ("APIs") to be used in opioid drugs.

113. Johnson & Johnson owned a subsidiary based in Tasmania, Tasmanian Alkaloids Limited ("Tasmanian Alkaloids"), which cultivated and processed opium poppy plants to manufacture narcotic raw materials that were imported into the U.S. to be processed and made into APIs necessary to manufacture opioid drugs.

114. Johnson & Johnson also owned a subsidiary based in the U.S., Noramco, Inc. ("Noramco"), which imported the narcotic raw materials produced by Tasmanian Alkaloids, processed these materials into APIs, then sold these APIs to other opioid manufacturers in the U.S.

115. Up until 2016 when Johnson & Johnson sold Noramco and Tasmanian Alkaloids, Tasmanian Alkaloids and Noramco were sister companies, as both of them were members of Janssen's "family of companies." Janssen, Noramco, and Tasmanian Alkaloids shared employees and resources that were required to operate the business. Noramco employees

physically worked at Janssen's facilities in New Jersey at various times. Further, employees simultaneously held positions at multiple companies within the Johnson & Johnson family of companies at times.

116. During this time, Noramco and Tasmanian Alkaloids were key parts of Janssen's "pain management franchise" or "pain franchise." This "pain franchise" included all of Janssen's pain products and was an important part of Janssen's business from the mid-1990s to after 2010.

117. Janssen, through these subsidiaries, supplied the following opioid APIs to other drug manufacturers in the U.S., including Purdue and Teva: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.

118. Johnson & Johnson's ownership of these subsidiaries uniquely positioned its pain management franchise to provide U.S. drug manufacturers, including Johnson & Johnson itself, with a reliable supply of and direct access to narcotic raw materials.

119. In 1994, Janssen, in concert with its subsidiary Tasmanian Alkaloids, anticipated demand for oxycodone. Specifically, Janssen's scientists at Tasmanian Alkaloids began a project to develop a high thebaine poppy variety to meet anticipated demand. The result of Janssen's research project was the creation of the "Norman Poppy," which Janssen internally described as "a transformational technology that enabled the growth of oxycodone."

120. In 1994, Purdue filed its new drug application ("NDA") for OxyContin. Through Noramco, Janssen met the anticipated opioid demand by selling APIs, including oxycodone, to Purdue.

121. Through Noramco, Janssen also supplied APIs to other opioid manufacturers, including Teva. Noramco sold the majority of its products pursuant to long-term agreements it had with all seven of the top U.S. generic companies.

122. By 2015, Janssen's "Noramco World Wide Narcotics Franchise," comprised of Noramco and Tasmanian Alkaloids, had become the top supplier of narcotic APIs in the U.S., the world's largest market.

Janssen misled providers and patients about the risk of opioid addiction

123. Janssen misled health care providers and patients about the adverse effects of opioids, particularly the risk of addiction.

124. Janssen disseminated deceptive messages about its opioid products as early as the 1990s, and has been on notice of its deceptive marketing since at least 2000. In a letter dated March 30, 2000, the FDA informed Janssen that its promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."

125. That letter identified specific misrepresentations Janssen made that Duragesic had a low potential for abuse:

> You present the claim, 'Low abuse potential!' This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, 'Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine.' Therefore, this claim is false or misleading.

126. In 2001, Janssen was advised by its own hired scientific advisory board that many of the marketing messages Janssen used to promote opioids in general, and Duragesic specifically, were misleading and should not be disseminated. Specifically, the advisory board advised Janssen not to market opioids, including Duragesic, using messages related to abuse or with claims about supposedly low abuse potential.

127. Janssen was advised that no data existed that could support these claims, that the data Janssen pointed to did not support these claims, that aggressively marketing OxyContin on this

same basis was what had gotten Purdue "in trouble," that minimizing the risk of abuse of Duragesic was "dangerous" due to its lethal nature, and that an increase of Duragesic sales would cause an increase in abuse of and addiction to the drug. The advisory board concluded: "Do not include the abuse message. Do not sell opioids on the abuse issue."

128. In 2004, the FDA sent Janssen a letter stating that a card Janssen used to promote Duragesic contained "false or misleading claims about the abuse potential and other risks of [Duragesic], and include[d] unsubstantiated effectiveness claims for Duragesic." The FDA found that the card misbranded the drug by "suggesting that Duragesic has a lower potential for abuse compared to other opioid products," and that the card "could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation."

129. Additionally, although there was no credible scientific evidence establishing that addiction rates were low among patients who took opioids such as Nucynta to treat chronic pain, Janssen concluded that one of the "drivers" to sell more Nucynta among primary care physicians was the "[l]ow perceived addiction and/or abuse potential" associated with the drug.

130. Janssen also trained its sales force to trivialize addiction risk. A 2009 Nucynta training module warns that physicians are reluctant to prescribe controlled substances like Nucynta because of their fear of their patients becoming addicted, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed."

131. [redacted]

132. In another example of Janssen's minimizing of addiction risks, Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient's

fear that "I'm afraid I'll become a drug addict." Janssen's response was that "[a]ddiction is relatively rare when patients take opioids appropriately."

133. In a November 2008 training presentation, Janssen instructed its sales representatives to avoid the so-called "addiction ditch" in sales calls—i.e., to avoid the downsides of opioid use (addiction) and instead reframe the conversation as being about how addiction concerns contribute to the undertreatment of pain—and to use a study from Dr. Portenoy "to create dialogue about Opiophobia as a barrier."

134. Janssen also funded, provided input on, and distributed third party publications of doctor and patient "educational" materials that misled their target audiences about the danger of prescription opioids. These publications downplayed the true risk of addiction and asserted that patients should be persistent in getting opioids for their pain. For example:

Finding Relief

135. Janssen worked with the American Academy of Pain Medicine ("AAPM"), now known as the Academy of Integrative Pain Management, and the American Geriatrics Society ("AGS") to sponsor, create, and distribute a patient education guide entitled *Finding Relief: Pain Management for Older Adults*(2009) ("*Finding Relief*").

136. Janssen exercised control over *Finding Relief's* content and provided substantial assistance to AGS and AAPM to distribute it. [redacted] indicates that key personnel from Janssen's advertising and promotion, health care compliance, legal, medical affairs, medical communications, and regulatory departments reviewed and approved *Finding Relief.*

137. *Finding Relief* deceptively described as "myth" the claim that opioids are addictive, and asserted that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." (Emphasis in original).

138. *Finding Relief* also deceptively described as "myth" the claim that opioid doses increase over time "because the body gets used to them," and asserted that "[u]nless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time."

139. While *Finding Relief* described the adverse effects of taking aspirin, acetaminophen, and NSAIDs at high doses, the guide made no mention of the potential risks of increased opioid dosages, implying that opioids are safer or have fewer adverse effects than these over-the-counter drugs.

140. [redacted]

Exit Wounds

141. Janssen provided grants to distribute an American Pain Foundation ("APF") book, *Exit Wounds* (2009), which sought to reassure veterans about addiction concerns regarding opioids by explaining that although they may become physically dependent on opioids, they will not become addicted.

142. *Exit Wounds* taught veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain

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

143. *Exit Wounds* stated that "[o]pioid medications can, however, be abused or used as recreational drugs, and some people who use drugs in this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing them harm." (Emphasis in original.)

Opioid Prescribing

144. Janssen co-funded a medical education guide, *Opioid Prescribing: Clinical Tools and Risk Management Strategies* ("*Opioid Prescribing*"), which was authored by three members of the board of directors of the AAPM, one of whom served as a paid consultant to Janssen. The guide was intended to reach primary care physicians and other health care professionals.

145. *Opioid Prescribing* minimized risks associated with opioid addiction, teaching prescribers, for example, that "fear of addiction and abuse prevents physicians from properly prescribing opioids, particularly for those with a substance abuse history who could benefit from opioids[.]" The guide deceptively instructed providers to give patients who present symptoms of "pseudoaddiction" more pain treatment—in other words, higher or more frequent dosages of opioids—because "[w]hen pain is treated appropriately, aggressive drug-seeking behavior ceases."

146. However, disseminating the concept of pseudoaddiction, without including clear messaging about the appropriate response to aberrant patient behaviors, led prescribers to continue opioid therapy or even raise dosages of opioids they had prescribed to patients when the dosage should have been tapered or stopped.

147. *Opioid Prescribing* told providers that patients who use opioids to "cope with stress [or] relieve anxiety," or even patients who "use opioids to get high, but ... not...in the compulsive way," are not exhibiting signs of addiction, but rather are displaying "other forms of aberrant drug use."

148. *Opioid Prescribing* further provided that even "behaviors that suggest abuse," such as "unscheduled visits, multiple telephone calls to the clinic, unsanctioned dose escalations, obtaining opioids from more than one source, selling prescription drugs, and forging prescriptions," may not be signs of addiction, but rather "may only reflect . . . having pain that is undertreated."

Let's Talk Pain

149. Starting from at least 2008, Janssen also helped form a "coalition" with APF, AAPM, and the American Society for Pain Management Nursing ("ASPMN") in the fight to promote opioid use. Specifically, Janssen and these organizations entered into a partnership to "keep pain and the importance of responsible pain management top of mind" among prescribers and patients, working to reach "target audiences" that included patients, pain management physicians, primary care physicians, and key opinion leaders ("KOLs").

150. Part of the coalition's efforts included creating a website in 2009, letstalkpain.org, which was directed at patients and providers, including in Illinois, and financed and maintained by Janssen.

151. Janssen exercised substantial control over the content of the *Let's Talk Pain* website, and used it to promote Nucynta. In fact, Janssen regarded letstalkpain.org and another website, prescriberesponsibly.com (described further below) as integral parts of Nucynta's launch campaign.

152. One of Janssen's roles was to "[r]eview, provide counsel on and approve materials[,]" for the *Let's Talk Pain* website. Even though the website was hosted by APF, consulting agreements and internal correspondence confirm that Janssen had approval rights over its content.

153. The *Let's Talk Pain* website deceptively told consumers that "the stigma of drug addiction and abuse" associated with the use of opioids was "harmful" and stemmed from a "lack of understanding about addiction."

154. The website also promoted the spurious concept of "pseudoaddiction," which it described as "patient behaviors that may occur when pain is under-treated," but which differs "from true addiction because such behaviors can be resolved with effective pain management."

155. The *Let's Talk Pain* website claimed that the use of opioids for the treatment of chronic pain would lead to patients regaining functionality and featured an interview claiming that opioids were what allowed a patient to "continue to function."

156. Furthermore, as part of the *Let's Talk Pain* mission, Janssen produced and disseminated consumer-directed videos through its affiliation with the coalition. These videos were designed to encourage patients to seek treatment with opioids for chronic pain. For example, one such video titled "Safe Use of Opioids," overstates the benefits of chronic opioid use and fails to mention the risks of addiction and abuse associated with opioids.

157. Another video warned that "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say: "Because of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients . . . . This prescribing condition is one of many

barriers that may contribute to the under-treatment of pain, a serious problem in the United States." These assertions reinforced the false message that the risks of addiction and abuse were insignificant and overblown.

158. [redacted]

159. [redacted]

160. [redacted]

161. These messages misleadingly downplayed and encouraged consumers to ignore the risk of addiction.

162. [redacted]

PrescribeReponsibly.com

163. Another Janssen-controlled unbranded marketing project was a website called prescriberesponsibly.com. This website was aimed at both prescribers and patients, including in Illinois, and a disclaimer at the bottom of the website stated that the "site is published by Janssen Pharmaceuticals, Inc., which is solely responsible for its content."

164. Janssen's prescriberesponsibly.com website contained numerous articles that misrepresented, trivialized, or failed to disclose the known risks of opioid products. For example, one article dismissed concerns about opioid addiction as "often overestimated," and proclaimed that "[t]rue addiction occurs in only a small percentage of patients . . . who receive chronic opioid analgesic therapy."

165. Other articles on prescriberesponsibly.com misleadingly instructed prescribers and patients that:

a. Addiction risk screening tools allow providers to identify patients predisposed to addiction, thereby purportedly allowing prescribers to manage the risk of opioid addiction in their patient populations.

b. "In those cases when a patient expresses concern about addiction," it is important to have a further discussion, because if the concern turns out to be "physical dependence," the patient's addiction concerns can be overcome by "reassurance from the healthcare professional."

c. Addiction might actually be "pseudoaddiction," defined as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed," and "[t]ypically when the pain is treated appropriately, the inappropriate behavior ceases."

Current Concepts in Pain Management

166. In 2010, Janssen funded and developed a newsletter publication targeting nurses called *Current Concepts in Pain Management* ("*Current Concepts*") in an effort to market and promote the use of Nucynta.

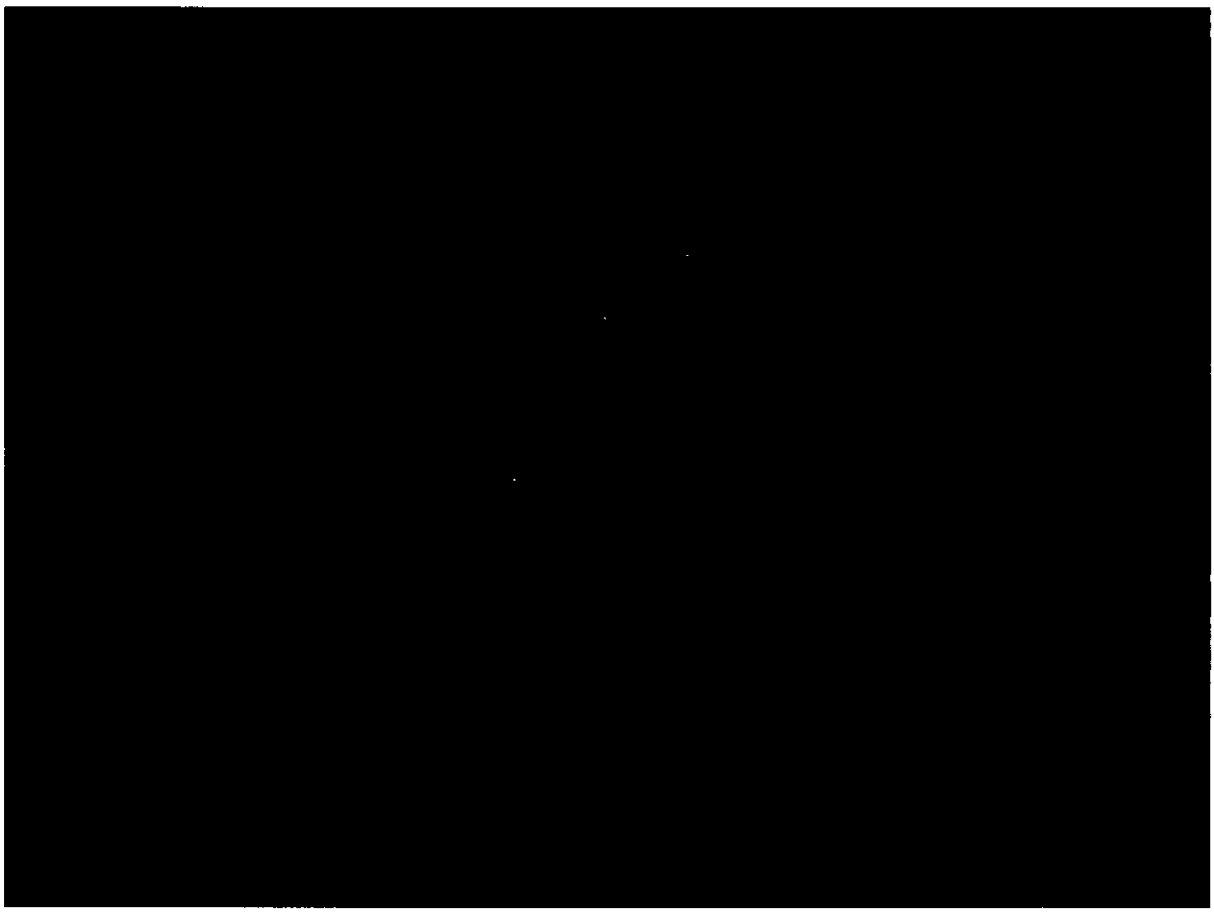
167. [redacted]

168. The nurses who provided content for *Current Concepts* were paid consultants for Janssen and compensated for serving as authors and editors for *Current Concepts*.

169. In an effort to encourage nurses to prescribe Nucynta more often, [redacted]

170. Using admonitions like those described above, Janssen encouraged nurses to exercise less caution in prescribing opioids by both downplaying the risks of prescribing them and overstating the harm from *not* prescribing opioids.

171. [redacted]



172. In an effort to further reduce nurses' reservations about their patients becoming addicted to opioids, the second issue of *Current Concepts* included an interview with a nurse who expressed surprise that other nurses were still concerned about "drug seekers," "frequent flyers," and "clock watchers," stating that she "really thought we were past all those terms" as if those concerns were outdated or should be disregarded.

173. In that same interview, the nurse in *Current Concepts* asserted that nurses should be educated on "the differences among addiction, dependency, and tolerance." She claimed that nurses are failing by "overestimat[ing] the safety of NSAIDs" and "demonstrat[ing] insecurity about . . . opioids in general, and any relation to addiction potential."

174. Elsewhere in the newsletter, the executive editor cautions nurses against worrying about addiction, in part because "withholding opioids from a person with severe pain can produce

physical and mental harm as well as maladaptive behaviors in patients who do not have true addiction (i.e., pseudoaddiction)."

175. Notwithstanding Janssen's efforts to promote the idea of "pseudoaddiction," the 2016 CDC Guideline confirms the invalidity of the concept, explaining that "patients who do not experience clinically meaningful pain relief early in treatment (i.e. within 1 month) are unlikely to experience pain relief with longer-term use."[82] The Guideline went on to advise that prescribers should "reassess[] pain and function within 1 month" to decide whether to "minimize the risks of long-term opioid use by discontinuing opioids." Thus, contrary to Janssen's representations, the Guideline advises that physicians should consider *discontinuing* opioid use for those patients who are exhibiting behaviors that indicate ineffective pain relief, not *increasing* their doses.

Janssen deceptively downplayed the symptoms of withdrawal and the ability to manage them

176. Janssen downplayed the difficult and painful effects that many patients experience when dosages are lowered or opioids are discontinued, which decrease the likelihood those patients will be able to stop using opioids.

177. For example, Janssen trained its sales representatives to misrepresent the prevalence of withdrawal symptoms associated with Nucynta. Multiple training modules instructed that the purported "low incidence of opioid withdrawal symptoms" is a "core message" for its sales force. This message was touted at Janssen's Pain District Hub Meetings, at which Janssen periodically gathered its sales teams to discuss strategy.

178. Janssen's "Licensed to Sell" Facilitator's Guide instructed those conducting Janssen sales trainings to evaluate trainees, in part, on whether they remembered that "[w]ithdrawal symptoms

[82] Dowell, *supra* note 15, at 2.

after abrupt cessation of treatment with NUCYNTA ER were mild or moderate in nature, occurring in 11.8% and 2% of patients, respectively" and whether they were able to "accurately convey" this "core message."

179. Some training modules even instructed training attendees that "most patients [who discontinued taking Nucynta] experienced no withdrawal symptoms" and "[n]o patients experienced moderately severe or severe withdrawal symptoms."

180. Janssen sales representatives adopted these training instructions and told Illinois prescribers on numerous occasions that patients on Janssen's drugs were at low risk for experiencing withdrawal symptoms. For example:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

181. According to Janssen's call notes, [redacted]

182. Furthermore, according to Janssen's sales call notes, [redacted]

Janssen deceptively promoted Nucynta ER as tamper-resistant and therefore less likely to be abused

183. Janssen misleadingly promoted Nucynta ER as tamper-resistant and less likely to be abused.

184. According to internal documents, [redacted] touted media coverage stating that "the new form of NUCYNTA ER" had "been changed to increase the resistance to crushing or breaking."

185. However, Nucynta ER never received FDA approval to include language asserting crush- or abuse-resistant properties in the drug's product label.

186. Nevertheless, Janssen continued to market Nucynta ER's purported tamper-resistant properties. According to internal correspondence [redacted]

187. In another internal correspondence [redacted]

[redacted] Janssen thus recognized that providers and patients might *perceive* a tamper-resistant formulation to be abuse-deterrent, even if being tamper-resistant does not necessarily give a drug abuse-deterrent properties.

188. [redacted]

Doing so created the false impression that Nucynta ER's purported crush-resistant nature also made it abuse-deterrent.

Janssen misrepresented opioids' ability to improve function and quality of life

189. Available evidence indicates opioids do not improve function or quality of life when taken long-term – indeed, they may harm patients' health.[83]

190. Nevertheless, Janssen made deceptive and unsubstantiated claims regarding the improved quality of life and function resulting from opioids in general and its own drugs in particular.

191. For example, in September 2004, the FDA sent Janssen a letter detailing a series of unsubstantiated, false or misleading claims regarding Duragesic's effectiveness regarding improved functionality and other benefits, and concluded that various claims made by Janssen were insufficiently supported, including:

a. Demonstrated effectiveness in chronic back pain with additional patient benefits … 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep."

b. "All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain."

[83] *See, e.g.*, Andrea D. Furlan *et al.*, *Opioids for Chronic Noncancer Pain: A Meta-analysis of Effectiveness and Side Effects*, 174 Canadian Med. Ass'n J. 1589 (2006); *see also* Dersh et al., *supra* note 75.

c. "Significantly reduced nighttime awakenings."

d. "Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index."

e. "Significant improvement in physical functioning summary score."

f. "Chronic pain relief that supports functionality."

192. Although opioids can initially improve function by providing pain relief in the short term, there is no evidence that opioids improve patients' function in the long-term.

193. Despite the lack of evidence of improved long-term function, Janssen continued to deceptively promote opioids as improving function and quality of life without disclosing the lack of evidence for this claim. For example:

Finding Relief

194. *Finding Relief*, created and distributed by Janssen, described as "myth" the claim that opioids make it harder to function normally. *Finding Relief* also asserted that "[w]hen used correctly for appropriate conditions, opioids may make it *easier* for people to live normally." (Emphasis in original). The guide stated that opioids can help people with chronic pain "get back to work, walk or run, play sports, and participate in other activities."

195. [redacted]

Exit Wounds

196. Janssen provided grants to distribute *Exit Wounds*, which taught veterans that opioid medications "increase your level of functioning."

Janssen deceptively pushed prescribers to increase opioid doses

197. The ability to escalate doses was critical to Janssen's efforts to market opioids for long-term use. Unless health care providers felt comfortable prescribing increasingly higher doses of opioids to counter their patients' building of tolerance to the drugs' effects, they may not have chosen to initiate opioid therapy at all.

198. [redacted]

199. Janssen sales representatives employed the above tactics when visiting with Illinois prescribers, encouraging them to increase the doses of its opioids rather than prescribe them more frequently, despite the increased risk of addiction. For example:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

[redacted]

e. [redacted]

f. [redacted]

Janssen deceptively sought to keep patients on opioids for as long as possible

200. Janssen's misrepresentations regarding the risk of addiction, the signs of addiction, the ability of opioids to improve function and quality of life, and the safety of higher doses of opioids were all part of the bigger picture of keeping patients on Janssen's opioid products for longer and longer periods of time.

201. Janssen's "$25 savings card" program was one method through which it was able to increase the number of long-term opioid users.

202. [redacted]

203. Janssen also distributed "10 free pill vouchers," which Janssen used to attract new users and offset cost objections. For example:

a. [redacted]

b. [redacted]

c. [redacted]

204. Janssen committed substantial resources to its savings card and free pill voucher programs. [redacted]

Janssen deceptively compared the risks and benefits of its products with those of competing opioids and alternative forms of pain treatment

205. As another element of its marketing plan, Janssen made claims that competing products were more dangerous than they actually were, less effective than they actually were, or that its products were equivalent to or superior to competing opioids when these claims were false, deceptive and/or unsubstantiated at the time they were made.

206. Janssen's internal business plans reveal that starting in 2009, it sought to create demand for Nucynta among patients and prescribers by stoking dissatisfaction with other pain treatments. Janssen referred to this effort as a "need to disrupt satisfaction by highlighting an unmet need," as a desire to "redefine pain management success," and as an effort to "disrupt [the] chronic [pain] market."

207. One method Janssen used in an attempt to distinguish itself from competitors was to promote the idea that Nucynta had a dual mechanism of action. Evidence from *preclinical animal studies* suggested that efficacy of tapentadol was thought to be due to two separate actions: (a) mu-opioid receptor agonism, meaning that it activates an opioid receptor; and (b) norepinephrine reuptake inhibition ("NRI"), meaning that it impacts neurotransmitters (such as norepinephrine) that communicate between brain cells.

208. The FDA has warned that such preclinical studies are of limited utility and are "not a substitute for studies of ways the drug will interact with the human body."

209. Janssen nevertheless marketed Nucynta as having a dual mechanism of action, *i.e.*, that the drug acts as both an opioid and a NRI. Janssen extensively relied on this unproven dual mechanism of action to deceptively portray Nucynta as a mild opioid that is less addictive than other Schedule II opioids such as OxyContin and offers additional benefits that other opioids do not. For example, Janssen often described tapentadol as offering "mu-receptor sparing benefits," or having a "dual [mechanism of action that] potentiates mu-sparing properties," or as providing a "multi-pathway approach [that has] mu receptor sparing effects."

210. Janssen also [redacted]

211. Janssen used these cards and the preclinical studies to represent, without adequate supporting evidence, that Nucynta's dual mechanisms of action ("MOA") would be more effective than alternative medications for treating certain types of pain and certain types of patients, including those suffering from radiculopathy. For example, in Illinois:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

g. [redacted]

h. [redacted]

212. According to Janssen's call notes, [redacted]

213. In making these representations, Janssen routinely obscured or failed to disclose that Nucynta's exact mechanism of action is unknown and that the company's representations regarding the drug's dual mechanism of action were supported only by limited evidence gleaned from preclinical animal studies.

214. [redacted]

215. Janssen thus deceived prescribers into believing that Nucynta was *proven* to be more effective or otherwise superior to competing opioids.

216. In another effort to draw misleading comparisons between its products and alternatives, Janssen created and/or distributed written materials to warn providers about the dangers of too much acetaminophen or NSAIDs.

217. A 2010 issue of *Current Concepts* included an article written by a paid Janssen consultant purporting to review "the Adverse Effects of Pain-Relieving Drugs" with sections on nonopioid analgesics. The section on NSAIDs opened with the claim that "[a]n estimated 16,500 deaths per year in the United States are attributed to NSAIDs in patients with arthritis alone." The section went on to detail the potential for ulcerations and internal bleeding, and to highlight the risks of adverse effects for "[a]dvanced age use."

218. However, the CDC has made clear that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain. An independent scientific study in 2018 echoed these findings, concluding that: "[t]reatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."

219. *Current Concepts* also warned that the use of acetaminophen "may be associated with liver injury" and that "close monitoring may be needed" because "the onset of liver injury can be hard to recognize."

220. However, in its section on opioids, the newsletter omitted any mention of risks to advanced-age patients and made no mention of potential abuse or addiction. Instead, it

mentioned potential side effects, then offered a variety of solutions for how to "reduce the risk of adverse effects" in a clear effort to promote the use of opioids over nonopioid options. Emphasizing the number of deaths caused by NSAIDs, but failing to even mention the risk of addiction and death resulting from the use of opioids gave the deceptive impression that opioids are safer than NSAIDs.

221. Janssen also provided grants to distribute *Exit Wounds,* which emphasized "concern in the medical community about the growing rate of liver damage associated with large doses of acetaminophen." However, the publication omitted, for instance, warnings about potentially fatal interactions between opioids and anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder – the target audience for *Exit Wounds*.

222. Janssen supported this marketing effort to target veterans, despite acknowledging on the label for Duragesic in 2008 that its use with benzodiazepines "may cause respiratory depression, hypotension, and profound sedation or potentially result in coma."

Janssen targeted its deceptive claims at senior citizens

223. Janssen also targeted the elderly in marketing its opioids.

224. Janssen misrepresented the safety of its opioid products for the elderly, including by emphasizing senior citizens as lower-risk patients and omitting the material fact that there is a greater risk of respiratory depression from opioids in elderly patients.

225. For instance, Janssen worked with AGS to promote 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons* ("AGS Guidelines"). The Janssen-sponsored AGS Guidelines represented that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse," even though the study supporting this assertion did not analyze addiction rates by age.

226. [redacted]

227. Janssen also instructed its sales representatives [redacted]

228. However, sales representatives did not adequately disclose the risks of prescribing opioids to elderly patients [redacted]

229. Elderly patients are at higher risk for the most dangerous side effect of opioids—respiratory depression. They also are likely to experience more severe consequences from falls (fractures and hospitalizations) caused by the cognitive impairment that is associated with opioid use. A 2010 paper reported that elderly patients who used opioids had a significantly higher rate of deaths, heart attacks, and strokes than users of NSAIDs.

Janssen used branded and unbranded marketing targeted at Illinois providers and patients to disseminate its misleading messages

230. Janssen pushed all of these deceptive messages in ways strategically designed to deceive providers and patients. Janssen sent its sales representatives to have one-on-one visits with providers to persuade them to prescribe more Janssen opioids. Janssen also authored and disseminated both its own branded materials, as well as unbranded materials from third-party groups that Janssen funded but which were designed to look independent.

231. To execute its marketing strategy, among other tactics, Janssen deployed sales representatives to convey its opioid messaging directly to Illinois prescribers in their offices, often with a free lunch, to persuade them to prescribe the drug as frequently as possible.

232. Janssen identified at least 2,820 prescribing offices in Illinois for detailing from 2007 through 2013, and met with at least 5,340 different Illinois prescribers at least once between 2007 and 2013 to promote Nucynta.

233. Janssen focused its sales calls on high-prescribing physicians [redacted]

234. Janssen knew the value of targeting high-prescribers, [redacted]

235. Janssen also has an active grant program supporting third party organizations. Janssen has provided organizations with more than $5.9 million in payments, including:

a. $573,570.00 to AAPM
b. $1,895,029.00 to the American Pain Society
c. $635,100.00 to APF
d. $605,626.00 to AGS
e. $100,000.00 to the American Chronic Pain Association
f. $805,000.00 to the The National Pain Foundation
g. $155,840.00 to the Pain and Policies Study Group
h. $329,824.00 to the American Society of Pain Management Nursing
i. $265,855.00 to the Academy of Integrative Pain Management
j. $23,000.00 to the Center for Practical Bioethics
k. $545,244.00 to the Joint Commission

236. Pharmaceutical companies, including Janssen, provided almost all of the funding for APF, which provided publications to health care providers, patients, policymakers and journalists. APF's materials contain misrepresentations about opioids.

237. In addition to selecting and funding third parties to conduct marketing campaigns, Janssen also incentivized aggressive sales tactics by paying sales representatives bonuses based on the number of prescriptions for Nucynta written by the prescribers they visited. For example,

[redacted]

238. [redacted]

239. [redacted]

240. Janssen also hired, trained, and deployed providers as part of its speakers' bureau to promote Nucynta, paying them to present Janssen materials containing deceptive information about the risks, benefits, and superiority of Nucynta. For example, a presentation offered throughout 2011 entitled *A New Perspective for Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* minimized the risks of withdrawal by stating that "more than 82% of subjects treated with tapentadol IR (Nucynta) reported no opioid withdrawal symptoms."

241. An August 2011 speaker presentation titled *New Perspectives in the Management of Moderate to Severe Chronic Pain* similarly minimized the risks of withdrawal by reporting that 86% of patients who stopped taking Nucynta ER "abruptly without initiating alternative opioid therapy" reported no withdrawal symptoms whatsoever.

242. The same deceptive claims regarding risks of adverse events and withdrawal appeared in a July 2012 speaker's presentation titled *Powerful Pain Management: Proven Across Multiple Acute and Chronic Pain Models*.

243. Janssen's speaker events typically occurred at upscale restaurants, with dinner and drinks paid for by the company. An invitation to join the speakers' bureau was both a reward for writing Nucynta prescriptions—because speakers were well compensated by Janssen—and an incentive to continue writing prescriptions [redacted]

244. Furthermore, Janssen targeted doctors in Illinois who ultimately faced disciplinary proceedings or criminal prosecution. [redacted] In April 2010, the Illinois Department of Financial and Professional Regulation ("IDFPR") filed suit to suspend this physician's medical licenses, alleging that the physician prescribed large quantities of controlled substances "without therapeutic purpose and without proper evaluations" of patients, prescribed narcotics to patients who then sold them on the street, and traded medications to a patient in exchange for sex. The physician's license was revoked in June 2011.

245. Janssen also used unbranded marketing to increase opioid use by pushing the message that under-treated acute pain would inevitably turn into chronic pain.

246. [redacted]

Janssen's unfair and deceptive marketing increased the sales of its APIs and generic opioid products

247. Janssen's efforts in support of its branded drugs, as well as Janssen's unbranded marketing, inevitably impacted sales of opioids in general, including generic opioids which Janssen knew health care providers would frequently prescribe or dispense in place of branded products.

248. This expanded the demand for Janssen's APIs, as well as generic opioids, such as the generic version of Duragesic that Janssen manufactured.

249. Through its unfair and misleading marketing, Janssen sought to expand overall demand for these dangerous drugs, fueling abnormally high levels of opioid prescribing and unprecedented levels of diversion, addiction, and death.

Endo

250. Endo has an extensive history of marketing and selling opioids. In 1950, Endo launched an oxycodone and aspirin combination product called Percodan. In 1971, it launched Percocet, an immediate release oxycodone and acetaminophen combination product. Endo subsequently launched new strengths of Percocet in 1999 and 2001.

251. In 1959, Endo also launched Numorphan, an immediate release oxymorphone product. Oxymorphone is the same active ingredient in Opana ER. Endo voluntarily withdrew Numorphan from the market in 1982, due, in part, to reports that people were abusing the drug via injection.

252. Endo launched Opana ER, an extended release oxymorphone product, in the second half of 2006 and subsequently received FDA approval for and transitioned to a crush resistant formulation of Opana ER in 2012. Endo sought to make Opana ER its "flagship brand."

253. Endo also manufactured and sold various generic opioid products.

254. Endo disseminated numerous unfair, deceptive and unsubstantiated claims regarding opioids generally and Endo's opioid products specifically, including that opioids have minimal addiction risk, improve patients' quality of life and function, and that Endo's opioid products were less likely to be abused and were safer and more effective than competitor products.

255. Endo advanced these and other misleading concepts to doctors and patients, including in Illinois, in order to encourage the use of its opioids at higher doses over longer periods of time, and thereby maximize Endo's bottom line. [redacted]

Endo made deceptive claims about the likelihood of abuse and abuse-deterrent properties of Opana ER

256. As it was launching Opana, Endo was already well aware of the significant abuse potential of its drug and planned for how to respond to the possible "negative environment and PR crisis" that may be created from the "[m]isuse/abuse risk perception," and prepare itself for possible "crisis scenarios" such as the "death of abuser[s]," "[c]elebrity addiction mak[ing] news," a "Dateline NBC or 60 Minutes type investigation into the approval of another abusable opioid," or the "FDA send[ing] Dear Doctor letter to physicians with additional warnings about abuse potential of [Opana]."

257. Nevertheless, in 2007, soon after Opana ER's launch, marketing consultants hired by Endo created a presentation, "Better the Devil you Know… Inspiring Physicians to Do the Right Thing with Opana ER." [redacted] The presentation recommended positioning Opana as the "responsible" opioid that was "less attractive to drug seekers" and caused "less euphoria." These deceptive messages were advanced by Endo for years.

258. Endo's sales representatives conveyed these misrepresentations directly to health care providers, stating in sales calls that Opana ER had, for instance, "less abuse potential," "low incidence of euphoria," and was "very resistant to adulteration" and "not prone to abuse." Endo sales representatives sought to capitalize on health care providers' concerns regarding the risk of opioid abuse by, for instance, [redacted]

259. Endo's deceptive marketing worked. An internal 2008 brand strategy presentation noted that "[l]ow abuse potential continues as the primary factor influencing physicians' anticipated increase in use of OPANA ER."

260. After a reformulated version of OxyContin that was purportedly less prone to some forms of abuse was introduced in 2010, Endo recognized an opportunity to gain market share and quickly capitalized on this opportunity, noting internally that "[s]ignificant acceleration in recent OPANA ER TRx acquisition driven in part by customer dissatisfaction with new OxyContin formulation."

261. Endo knew that it was capitalizing off of people who were abusing or diverting opioids and had previously used OxyContin, noting internally both that competitive intelligence "identified abuse behavior [as] driving the decline in OxyContin use" and that "Opana ER [was] showing [the] most gain during OxyContin loss."

262. In July 2010, knowing that generic versions of Opana ER were set to come on the market which would cause "significant erosion" of the Opana ER franchise, and thus Endo's revenue stream, Endo submitted a supplemental new drug application ("sNDA") for a "reformulated" Opana ER that it claimed was designed to be crush resistant.

263. On January 7, 2011, an FDA Advisory Panel evaluating Endo's sNDA for the reformulated Opana ER found, among other things, that the new formulation showed "minimal" improvement in resistance to tampering by crushing, provided "limited resistance to physical and chemical manipulation for abuse," and that one study showed it may be "easier to prepare [as] a solution for injection" compared to the original formulation. The panel also noted that it was especially concerning that "when chewed...the new formulation essentially dose dumps like an immediate-release formulation."

264. As a result, the panel recommended that the product label for the reformulated Opana ER not include language asserting that the drug was crush or abuse resistant.

265. Endo subsequently discussed internally the possibility of funding an intranasal abuse study to differentiate the new formulation from the original version. Endo's Director of Project Management described how the proposal for such a study was previously "met with strong resistance" from the R&D Management Team. She explained that Endo's fear was "that there will be little differentiation between Opana CRF [crush resistance formulation] and Opana ER in an intranasal abuse study" given that previous studies had already shown little differentiation between the two formulations when both products were ground or chewed. As such, Endo could not "determine any valid scientific reason why the intranasal route would be any different." Thus, Endo feared that conducting such a study would just result in "yet a third study which shows no real incremental difference between old and new."

266. In December 2011, the FDA approved the reformulated Opana ER but determined that the label should not include language asserting the reformulation is crush resistant as it demonstrated "minimal improvement" over the original formulation for resistance to crushing and was "readily abusable by ingestion and intravenous injection, and possibly still by

insufflation; although whether [reformulated Opana ER] tablets can be snorted was not studied," as such the FDA determined that "the drug did not meet the agency's standards for being considered abuse-deterrent."

267. In a March 2012 internal report, summarizing data from late 2011, Endo noted that, [redacted] The report noted that [redacted] Endo also found [redacted]

268. In August 2012, in an effort to thwart generic competition, Endo filed a Citizen Petition with the FDA claiming it had removed the old version for "safety" reasons and requesting that the FDA suspend and withdraw approval for any generic versions of the old formulation. Endo put forth this safety concern over its old version of Opana ER even though Endo itself had recognized there was "little difference" between the old and new formulations when it came to abuse deterrence.

269. Early on after launching the reformulation, Endo became aware of concerning reports of abuse of the reformulated Opana ER, particularly by intravenous use, including reports of people developing a rare blood disorder known as thrombotic thrombocytopenic purpura or TTP as a result of intravenous abuse.

270. The FDA denied Endo's Citizen Petition in May 2013, stating that data did not support Endo's conclusions about the "alleged safety advantages" of the reformulated version relative to the original version, because the reformulated version will "dose dump" when it is subjected to cutting, grinding or chewing, and then swallowed, can be prepared for insufflation "using

commonly available tools and methods," and may be even "more easily [] prepared for injection" than the original formulation.

271. Also in May 2013, the FDA denied a sNDA that Endo had submitted seeking to add language to the label for reformulated Opana ER describing the results of abuse potential studies.

[redacted]

272. Despite all of this, Endo misrepresented that the reformulated Opana ER was safer than the original version, had abuse-deterrent properties, was crush resistant, remained intact or was otherwise resistant to abuse.

273. This deceptive marketing was particularly important in order for Endo to maximize profits for the reformulated version of Opana ER, since health care providers and others in the marketplace would likely choose the cheaper generic versions of the original formulation if the two formulations could not be clearly distinguished. Endo used this deceptive messaging to position reformulated Opana ER as safer than generic versions of the original formulation.

274. Internal brand strategy documents show Endo's plan to position reformulated Opana ER as having superior abuse deterrence properties to competing products, describing the brand vision as making reformulated Opana ER "the tamper resistant solution of choice based on having the most complete array of tamper resistant properties and the heritage of oxymorphone."

275. Endo rebranded the reformulated version as "Opana ER with INTAC Technology" to emphasize its purported abuse deterrence properties. In April 2012, the FDA sent a letter to Endo in response to the company's request for comments on a draft detail aid for the launch of reformulated Opana ER. The FDA recommended that the numerous references to and claims

about the reformulation's "INTAC technology" in the proposed detail aid be deleted, stating, among other things, that it was "especially concerned from a public health perspective because the presence of this information in the detail aid could result in health care practitioners or patients thinking that the new formulation is safer than the old formulation, when that is not the case."

276. Endo's response was to create a "sell sheet" with the same types of misrepresentations and emphasis on its INTAC technology. Endo knew such a piece had "some risk in negative reaction by [FDA]" but decided the benefits outweighed the risks.

277. A June 21, 2012 internal Opana ER Action Plan listed one of Endo's immediate opportunities for growth as the "[a]cceleration of key resources," and noted the company's plan to "[a]ccelerate field distribution of INTAC Sell Sheet."

278. Endo specifically trained its sales representatives to emphasize to physicians the crush-resistant nature and INTAC technology of the new formulation, despite knowing that the reformulated version could be easily cut or chewed and did not stay intact.

279. Similarly, when news reports surfaced detailing the rise in abuse of Opana ER, particularly a July 2012 USA Today story entitled "Opana Abuse in USA Overtakes OxyContin", Endo instructed its sales representatives to deceptively respond to any questions about the article from health care providers by communicating the "key point[]" that Endo had discontinued the original formulation of Opana ER and now "only manufactures the new formulation of Opana ER with INTAC technology which is designed to be crush resistant," even though Endo knew and had been explicitly told by the FDA just months earlier that there was no evidence to support the conclusion that the new formulation was safer than the original.

280. Endo continued to disseminate these misleading messages through marketing materials and sales calls, including to Illinois healthcare providers.

281. Endo also directed the physicians in its speakers bureau program to tell health care providers that [redacted]

282. Endo continued to be aware of evidence of significant abuse of the reformulated version of Opana ER, including an HIV outbreak in 2015 in a rural county of Indiana that was linked to intravenous abuse of Opana ER and data that showed rates of intravenous abuse of the reformulated Opana ER were *higher* than rates of abuse through snorting of the original formulation.

283. On June 8, 2017, the FDA took the unprecedented step of requesting that Endo remove the reformulated Opana ER from the market "due to the public health consequences of abuse."

284. Endo ceased shipments of Opana ER as of September 1, 2017.

Endo misled providers and patients about the risk of opioid addiction

285. Endo used branded and unbranded marketing to mislead health care providers and patients about the dangers of prescription opioids, particularly the risk of addiction.

286. Endo's own website for Opana, www.opana.com, contained misleading statements minimizing the risk of addiction, including a page called "About Opioids" which told consumers that "[m]ost doctors who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

287. Endo created a 2008 brochure titled "Taking a Long-Acting Opioid," that likewise told consumers that "patients treated with prolonged opioid medicines usually do not become addicted" and that "[t]aking opioids for pain relief is NOT addiction."

288. The same misleading message was contained in a guide Endo developed for caregivers called *Living with Someone with Chronic Pain*. This caregiver's guide stated that "[m]ost healthcare providers who treat people with pain agree that most people do not develop an addiction problem" when taking opioids. The guide was available, including to Illinois consumers, on the opana.com website as well as in brochure format.

289. Endo also used third-party groups and websites to disseminate similar misrepresentations. For instance, a 2007 fact sheet posted to the Endo-sponsored website, www.painknowledge.org, which was available for viewing by Illinois consumers, posed the question "will I become addicted to opioids?" and included in the answer that "[i]n general, people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted."

290. Endo also trained its sales representatives to disseminate these misleading messages. For instance, a 2010 training guide instructed sales representatives that "long-term opioid use can induce physical dependence and may induce tolerance to therapy" and that "[n]one of these physiological phenomenon cause addiction." The same training guide told Endo's sales representatives that it was "false" that "[a]ddiction to opioid medications is very common."

291. Endo's understating of the risk of addiction was misleading and was done with the intent that providers and patients would rely on it so providers would be more comfortable with prescribing opioids and patients more comfortable with taking them.

Endo made deceptive claims about the extent to which addiction risk can be managed and addiction prevented

292. As the 2016 CDC Guideline and other sources note, there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient agreements, or urine

drug testing "for improving outcomes related to overdose, addiction, abuse, or misuse."[84] Nevertheless, Endo told health care providers that they could effectively manage any addiction risk in their patients by using abuse and diversion mitigation tools.

293. Endo made these misleading claims through a website Endo operated called www.endopromise.com. The "PROMISE Initiative" stands for "The Partnership for Responsible Opioid Management through Information, Support, and Education."

294. Endo trained its sales representatives to tell health care providers that [redacted] Endo made the same representations on the PROMISE website itself.

295. Endo promoted the use of various screening tools, including through its funding of third-parties and speaker programs, overstating the efficacy of these tools to prevent or mitigate the risk of abuse and addiction. For instance, Endo funded and promoted the use of the Screener and Opioid Assessment for Patients with Pain or "SOAPP" [redacted]

296. The SOAPP questionnaire relied on patients' self-reported answers to 24 questions and told health care providers [redacted]

[84] Dowell, *supra* note 15, at 22-24.

297. Endo also promoted the use of the Opioid Risk Tool, a five question, one-minute screening tool that also relied on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease."

298. As another example, Endo funded a supplement available for CME credit in the *Journal of Family Practice* called "*Pain Management Dilemmas in Primary Care: Use of Opioids*." The section of the supplement titled "Use of Opioids" was authored by an Illinois physician and Endo consultant and, among other misrepresentations, deceptively minimized the risk of addiction by emphasizing the effectiveness of risk screening and patient monitoring tools, falsely claiming that with the use of such tools, even patients at high risk of addiction could safely receive chronic opioid therapy and "aberrant drug behaviors [can] be avoided." This CME was available and distributed nationwide, including to prescribers in Illinois.

299. Endo sought to reassure doctors that they could effectively manage any addiction risk in their patients by using abuse and diversion mitigation tools, even though there was not adequate evidence to support the effectiveness of such strategies.

Endo deceptively used terms like dependence, tolerance and "pseudoaddiction" to downplay the risk of addiction

300. Endo downplayed the problem of addiction by simply re-labeling it. Endo promoted the concept that signs of addiction are actually the result of untreated pain, which should be treated by prescribing even more opioids.

301. [redacted]

302. Endo taught sales representatives that "pseudoaddiction" described an "iatrogenic phenomenon in which a patient with undertreated pain is perceived by healthcare professionals to exhibit behaviors similar to those seen in addiction but is not truly addicted." According to Endo's training materials, "clock watching" or [redacted] of an opioid is an example of a pseudoaddictive behavior and physicians could differentiate between addiction and pseudoaddiction by "increasing the patient's opioid dose to increase pain relief."

303. Similarly, Endo taught sales representatives that both "physical dependence" and "tolerance" can be mistaken for addiction as well.

304. Endo continued to teach sales representatives to promote these misleading concepts for years, and even after they were publicly debunked.

305. Endo also funded third-party groups and websites to disseminate these deceptive claims. For instance, a 2007 fact sheet posted to the Endo-sponsored website, painknowledge.org, included a section called "opioid dictionary" which, among other things, included under the definition of "addiction" the statement that "[s]ometimes people behave as if they are addicted, when they are really in need of more medication. This can be treated with higher doses of medicine."

306. Endo also sponsored and distributed the 2007 book *Responsible Opioid Prescribing* which warns doctors to "[b]e aware of the distinction between *pseudo addiction* and addiction." (Emphasis in original). It explains that "[p]atients who are receiving an inadequate dose of opioid medication often 'seek' more pain medications to obtain pain relief," and "[t]his is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction."

307. The Endo-sponsored book lists examples of behaviors that are deemed "LESS indicative of addiction" including "hoard[ing] medications," "tak[ing] someone else's pain medications" and "us[ing] more opioids than recommended."

308. By comparison, the Endo-sponsored book identifies addiction-indicating behaviors as being much more extreme, including "[stealing] money to obtain drugs," "[p]erform[ing] sex for drugs," and "[p]rostitut[ing] others for money to obtain drugs."

309. Endo funded the production of the book and also contributed at least $200,000 to support the distribution of the book to state medical boards, including in Illinois.

Endo misrepresented opioids' ability to improve function and quality of life

310. Despite the lack of evidence of improved function with long-term opioid use, Endo made deceptive and unsubstantiated claims regarding the improved quality of life and function resulting from opioids in general and its own opioid products in particular.

311. For instance, the book *Responsible Opioid Prescribing* (2007), which Endo sponsored and distributed, taught that relief of pain itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function." The first page of *Responsible Opioid Prescribing* represents that patients "rely on opioids for . . . improved function."

312. In 2007, Endo was advised by a brand consulting firm to position Endo's own opioid product, Opana, as the opioid that "enables a better lifestyle to keep patients healthier."

313. Accordingly, Endo trained its sales representatives to use these deceptive claims when promoting Endo's opioid products. Sales training materials told representatives that [redacted]

314. Training materials also asked sales representatives whether it was true or false that "[t]he side effects of opioids prevent a person from functioning and can cause more suffering than the pain itself." The materials indicate this statement is "false" because "[t]he overall effect of treatment with opioids is very favorable in most cases."

315. Endo's sales representatives used deceptive claims to promote this concept to health care providers during sales calls, including communicating that Opana ER "improves sleep for the patient" [redacted]

316. An internal 2012 Business Plan continued to state that Endo's "Brand Vision" for Opana ER was to position it as "the choice that maximizes improvement in functionality."

317. Endo created marketing materials that communicated to health care providers that therapy with Opana ER would improve patients' ability to function, allowing them to return to work and improve physical activity. For instance, one brochure featured a fictional construction worker named Ray and described him as having "severe chronic lower back pain" but "need[ing] to work to support his family." The brochure for Opana ER concludes by telling health care providers that "Ray needs a chronic pain management plan that works—for you both."

318. Endo also used its support of the National Initiative on Pain Control ("NIPC") and its website www.painknowledge.com to disseminate similar deceptive and misleading messages. [redacted]

319. Contrary to Endo's claims, the 2016 CDC Guideline found no studies to support the effectiveness of long-term opioid therapy, versus placebo, no opioid therapy, or nonopioid

therapy, for outcomes related to pain, function and quality of life. In fact, the available evidence indicates opioids not only do not improve function or quality of life when taken long-term – but, indeed, they may harm patients' health.[85]

Endo deceptively pushed prescribers to increase opioid doses

320. Endo sold high strength doses of Opana ER in 20, 30 and 40 mg tablets, which represented a significant portion of Endo's business. Taking one Opana ER 20 mg tablet twice a day, or every 12 hours, is equivalent to 120 MMEs per day, which is 30 MMEs more than the 90 MME daily threshold recommended by the 2016 CDC Guideline. Taking one Opana ER 40 mg tablet twice a day amounts to 240 MMEs per day, well over twice the CDC recommended threshold.

321. Endo sought to make health care providers comfortable with prescribing its opioid products for longer periods of time and at higher and higher dosages. Unless health care providers felt comfortable prescribing opioids at increasingly higher doses to counter their patients' building of tolerance to the drugs' effects, they may have chosen to discontinue opioid therapy or not to initiate it at all.

322. Endo distributed a book written by Endo KOL Dr. Lynn Webster titled *Avoiding Opioid Abuse While Managing Pain* which told health care providers that, in the face of drug-seeking behavior, increasing the patient's opioid dosage "in most cases…should be the clinician's first response." Endo stated its goal in distributing the text was to "[i]ncrease the breadth and depth of the OPANA ER prescriber base."

323. Endo's marketing for Opana ER emphasized the availability of "five dosage strengths for individualized titration and dosing to help achieve adequate pain relief" and encouraged health

[85] *See, e.g.*, Furlan et al., *supra* note 83; Dersh et al., *supra* note 75.

care providers to "[t]itrate by 5-10mg every 12 hours every 3-7 days until adequate pain relief" was achieved, without disclosing the increased risks of taking higher doses of opioids.

324. Endo also promoted the idea, including through its speakers program, that there is no maximum or ceiling dose for its opioid products, other than that imposed by the patient's ability to tolerate side effects, again without disclosing the increased risks of taking higher doses of opioids.

325. Notably, after Endo launched the reformulated version of Opana ER, even more of its business came from higher doses of the drug. For instance, an internal business review from July 2012 showed that, for the week of June 29, 2012, the highest doses of Opana ER, 30 mg and 40 mg, accounted for 46% of the prescriptions for reformulated Opana ER as compared to 36% of the original version.

326. High dose opioids have continuously been a significant part of Endo's business in Illinois—particularly for Opana ER. [redacted]

327. Overall, evidence has shown higher opioid dosages to be associated with increased risks, including of motor vehicle injury, opioid use disorder, and overdose, and that the increased risk rises in a dose-dependent manner.[86]

Endo deceptively sought to keep patients on opioids for as long as possible

328. Just as with higher doses, the duration of opioid therapy has also been shown to be associated with increased risks, including for opioid use disorder.[87]

329. Even though opioids are most dangerous when taken long-term and at higher doses, continued, long-term use of its opioid products was central to Endo's business strategy.

[86]Dowell, *supra* note 15, at 22-24.
[87]Edlund, *supra* note 46.

330. Endo relied mainly on continued users as a source of business for Opana ER, noting in 2012, for instance, that 88% of the total prescriptions for Opana ER were continuing users.

331. Accordingly, Endo sought to encourage patients to stay on its opioid products as long as possible. For example, [redacted]

332. Similarly, in 2013, [redacted]

333. Endo also fueled sales of high doses and continued use of its opioid products through its Opana ER savings card program, the majority of which were used to purchase Opana ER tablets of 20 mg and higher. The savings cards worked like coupons to offset the cost of a prescription.

334. Endo knew its savings cards also helped patients stay on Opana ER, [redacted]

335. Helping patients take its opioid products at higher doses for longer periods of time was very lucrative for Endo. [redacted]

Endo deceptively compared the risks and benefits of its products and those of competing opioids

336. Endo made deceptive and/or unsubstantiated claims that Endo's products were equivalent to or superior to competing opioids, including that Endo's opioid products were safer and more effective than other opioid products.

337. Endo's comparison claims were not supported by competent scientific evidence.

338. Endo acknowledged internally that "there are no direct comparison studies of [reformulated Opana ER] to other opioid analgesics."

339. Nevertheless, from the launch of Opana ER, Endo was concerned with the drug being seen as a "me-too" product and identified "[d]ifferentiat[ing] OPANA ER based on durability of efficacy and dosing advantages" and "positively position[ing] OPANA ER vs. potential competitors" as imperative to the brand's success. Endo particularly sought to "[d]ifferentiate OPANA ER vs OxyContin," the market leader.

340. One way Endo sought to differentiate its opioid products was to convince health care providers that its products had less addictive potential and thus were safer than other opioid products. Endo did this by disseminating the deceptive claim that its products produced a lower rate of euphoria and fewer "peaks and troughs" compared to other opioid products.

341. For example, an internal 2008 presentation about brand positioning for Opana ER summarized the overall "promise" of Opana ER to be "[e]ffective pain relief without the complexities of OxyContin," and listed reasons to buy to include "low rate of euphoria" and "steady plasma levels."

342. Endo sales representatives carried these misleading messages directly to health care providers during sales calls, including by representing that Opana ER had a "low incidence of

euphoria," "fewer peaks and troughs," and that less euphoria when taking Opana means that patients "may be able to discontinue easier."

343. Endo also identified other comparative messages, including that Opana ER had "true" 12-hour dosing, fewer drug interactions, fewer side effects, and required less rescue medications, as ways to differentiate its product from opioid competitors.

344. These messages were disseminated through Endo's sales representatives when detailing health care providers. For example, in 2007, Endo knew that sales representatives were frequently making comparative claims, including by telling health care providers, among other things, that Opana ER:

a. "has a steadier release of the medication than most of the other medications out on the market";

b. "has less side effects";

c. [redacted]

d. Provides "better control of pain";

e. [redacted]

f. Has "less side effects and [is an] easier to take medication than OxyContin";

g. [redacted]

h. [redacted]

i. [redacted]

j. "[I]s safer than OxyContin"; and

k. Sales representatives had made "comparisons with other medications including OxyContin and generic morphine sulfate."

345. In 2011, Endo continued to focus on comparative claims to fuel the growth of Opana ER, noting in a market research report that [redacted]

[redacted]

346. Similarly, a 2011 evaluation of message recall in the marketplace found that 77% of health care providers recalled "true every 12 hour dosing" as the primary message of Opana ER sales representatives.

Endo targeted its deceptive claims at senior citizens

347. Endo focused on marketing its opioids to the elderly.

348. Endo targeted the above-described misrepresentations, particularly deceptive comparative claims, specifically with regard to the treatment of senior citizens.

349. For instance, Endo used the claim that Opana ER had greater efficacy, including "true" 12 hour dosing, and less drug interactions to target elderly patients who often take multiple medications. Endo focused on "elderly patients taking multiple meds, and those suffering from [osteoarthritis] and Chronic Low Back Pain."

350. One of Endo's marketing pieces for Opana ER highlighted "multiple medications" and "interaction challenges" using a vignette of a fictitious 76-year-old patient named Joan. Joan is described as suffering from osteoarthritis, taking concomitant medications and not having well controlled pain after 3 months of increased doses of opioids. [redacted]

351. In reality, elderly patients are at higher risk for the most dangerous side effect of opioids—respiratory depression. They also are likely to experience more severe consequences from falls (fractures and hospitalizations) caused by the cognitive impairment that is associated with opioid use.

352. Endo knew, based on Opana ER's own prescribing information, that Opana ER was to be used with caution in elderly patients and that a greater frequency of severe adverse events were observed in Opana ER patients ages 65 and older.

Endo used branded and unbranded marketing targeted at Illinois health care providers and patients to disseminate its misleading messages

353. Endo disseminated these deceptive and unfair messages directly to consumers and health care providers and indirectly through third-parties and speakers programs.

354. [redacted]

355. Endo focused its sales calls on high-prescribing physicians, including in the primary care setting. Its internal documents noted that its return on investment for sales calls to high decile prescribers was much greater than for lower decile prescribers.

356. Endo also emphasized marketing to nurse practitioners ("NPs") and physician assistants ("PAs"), noting that 96% of prescriptions they write are without a physician consult and 60% are new prescriptions. [redacted]

357. Endo knew that its sales calls influenced prescriber behaviors, noting in an internal market research report that "[a]ggressive detailing [is] having an impact" in the growth of sales of Opana ER. [redacted]

358. Endo also used third-party pain advocacy groups and its speakers programs to disseminate misrepresentations, including in Illinois.

359. Endo noted the effectiveness of its speakers program, stating that "physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than they had before they participated. You can't argue with results like that." Endo had complete control over the messages being conveyed by its paid speakers, [redacted]

360. Endo provided financial support to various third-party groups. Endo was one of the biggest financial supporters of APF. Between 1999 and 2012, Endo gave nearly $6 million to APF.

361. From 1999 to 2012 Endo gave the AAPM and American Pain Society ("APS") $1.3 million and $4.4 million, respectively. Endo also gave the American Geriatric Society over $340,000 between 2000 and 2011.

362. Endo funded and disseminated third-party materials that were designed to look independent, including treatment guidelines, which contained deceptive and misleading statements about opioids. These materials were distributed or made available in Illinois.

363. NIPC was also a key piece of Endo's marketing strategy and Endo used its financial support of NIPC and its website www.painknowledge.org to disseminate deceptive and misleading messages. [redacted] In or around 2009 NIPC became administered by APF.

364. Endo worked hard to ensure that NIPC materials would have the broadest possible distribution. In 2008 alone, Endo estimated that [redacted]

[redacted]

365. Endo also repeatedly detailed physicians who were ultimately arrested, convicted or received professional discipline for conduct related to their prescribing of controlled substances.

366. For example, one Illinois pain specialist [redacted] In January 2017, this pain specialist's license was placed on indefinite probation by IDFPR based on allegations that the doctor prescribed controlled substances for non-therapeutic purposes.

367. Another Illinois physician [redacted] This physician was indicted on federal charges of health insurance fraud in December 2012. Endo sales representatives called on him through January 2013. The physician was subsequently reprimanded and fined in April 2014 by IDFPR for issuing prescriptions without an Illinois Controlled Substance License and was barred from practicing in Michigan in July 2015. Nevertheless, Endo sales representatives [redacted] This physician's license was ultimately suspended by IDFPR in November 2016 for unprofessional conduct and distribution of controlled substances for non-therapeutic purposes. In December 2018, this physician was convicted by a jury on the federal fraud charges. Instead of recognizing and appropriately responding to red flags for suspicious prescribers, Endo removed only a small fraction of its

targeted providers from its call list. [redacted]

[redacted]

Endo's unfair and deceptive marketing increased the sales of its generic opioid products

368. Endo also had a significant generic opioids portfolio, which included generic versions of, among other drugs, OxyContin and MS Contin.

369. Endo's efforts in support of its branded drugs, as well as Endo's unbranded marketing, inevitably impacted sales of generic opioids which Endo knew health care providers would frequently prescribe or dispense in place of branded products.

370. Through its unfair and misleading marketing, Endo sought to expand overall demand for these dangerous drugs, fueling abnormally high levels of opioid prescribing and unprecedented levels of diversion, addiction, and death.

Teva

371. Prior to its acquisition in 2011, Cephalon, Inc. owned and conducted the business of marketing and selling Actiq and Fentora. Teva Ltd. acquired Cephalon, Inc. in 2011 and, since 2011, Teva Ltd., Teva USA, and Cephalon, Inc. have worked together closely to market and cell Cephalon products in the United States.

372. Teva's branded opioid products, Actiq and Fentora, are extremely powerful transmucosal immediate release fentanyl ("TIRF") drugs and are approved only for treatment of breakthrough cancer pain in opioid-tolerant patients already on around-the-clock treatment for pain.

373. Actiq is an oral transmucosal lozenge on a stick and was originally approved by the FDA in 1998. Cephalon acquired Anesta Corporation, the original creator of Actiq, in 2000 and re-launched Actiq in late 2000 or early 2001.

374. Fentora is a fentanyl buccal tablet that a patient places in their buccal cavity, or the area between the cheek and gum above a rear molar. Cephalon submitted a new drug application for Fentora in August 2005 and in September 2006 received FDA approval.

375. Both Actiq and Fentora were marketed by Teva as a new category of "rapid onset opioids" or ROOs, which Teva sought to differentiate from other short-acting opioids based on their rapid onset of analgesia.

376. Teva also manufactures and sells a significant number of generic extended release and immediate release opioid products, including oxycodone and oxymorphone hydrochloride.

377. Teva unfairly and deceptively promoted its branded opioid products, Actiq and Fentora, for widespread off-label use in patients without cancer.

378. Teva also disseminated numerous unfair, deceptive and unsubstantiated claims regarding opioids generally and Teva's opioid products specifically, including that opioids have minimal addiction risk, that signs of addiction are actually just "pseudoaddiction" and should be addressed by prescribing even more or stronger opioids, and that opioids improve patients' quality of life and function.

379. Teva advanced these and other misleading concepts to doctors and patients, including in Illinois, in order to encourage the use of its opioids at higher doses over longer periods of time, and thereby maximize Teva's bottom line.

Teva marketed Actiq and Fentora off-label to treat non cancer-related breakthrough pain

380. To ensure that prescription drugs sold in the United States are safe and effective, the Food Drug and Cosmetic Act ("FDCA") requires drug manufacturers to submit a NDA for all prescription drugs sold in the United States. The NDA must include clinical trials sufficient to prove to the FDA that the drug is safe and effective for each and every indication (use) for which the drug is sold.

381. If a manufacturer wants to market a drug for an indication not initially approved by the FDA, the company must submit a sNDA that demonstrates to the FDA that the drug is safe and effective for the new indication.

382. Although prescribers may use their own professional judgment to prescribe drugs for uses the FDA has not determined to be safe and effective, the FDCA makes it unlawful for companies to market drugs for indications the FDA has not approved ("off-label marketing").

383. Teva's branded opioid products, Actiq and Fentora, are extremely powerful immediate release fentanyl drugs and are approved only for treatment of breakthrough cancer pain in opioid-tolerant patients.

384. Fentanyl is a powerful synthetic opioid that is approximately 100 times more potent than morphine and 50 times more potent than heroin as an analgesic.

385. Actiq was approved for "the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

386. Likewise, in September 2006, the FDA approved Fentora for "the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

387. Finding the target population for the approved indications of its branded opioid drugs unacceptably small, Teva engaged in off-label marketing in order to claim a piece of the broader, more lucrative chronic, non-cancer pain market.

388. Teva used direct detailing by its sales representatives, speaker programs, continuing medical education programs, and other methods to promote and encourage the use of its extremely powerful opioid products, Actiq and Fentora, for treatment of non-cancer pain.

389. Teva's strategy for Actiq was clear from the start. In November 2000, Teva created a "Master Plan" for Actiq which included [redacted]

390. In accordance with this plan, Teva sales representatives made thousands of Actiq sales calls to health care providers unlikely to treat cancer-related pain at all, including those with specialties in Family Medicine and Rheumatology, and General Practitioners.

391. Teva's marketing plan for Actiq also made clear that [redacted]

392. [redacted]

393. Teva's own promotional guidelines provided that [redacted]

394. Starting in at least 2003, Teva sponsored the website "pain.com" which featured the company's logo on its homepage and contained numerous resources about research, support and treatment related to breakthrough pain generally, as opposed to breakthrough cancer pain. In at least 2005, the website included an article by Teva KOL Dr. Lynn Webster about the use of

Actiq to treat noncancer pain and in 2005 alone, [redacted]

395. Teva held and funded numerous Actiq Consultants Meetings, often in desirable locales, where health care providers could attend seminars and engage in "scientific exchange and discussion," often about the off-label use of Actiq.

396. Teva held multiple Actiq Regional Consultants Meetings at high-end hotels in Chicago which were attended by health care providers from around the Midwest, including Illinois. One Actiq Consultants Meeting was held at The Peninsula in Chicago in August 2003. [redacted]

397. As another example, the summary of a September 2003 Actiq Regional Consultants Meeting that took place in New York stated that [redacted]

398. A 2004 Actiq Publication Plan listed one of Teva's goals to be [redacted] This presentation goes on to describe [redacted]

[redacted]

399. A Teva brochure titled "A Pain Primer: A reference for the rest of us," which was used at least for sales training purposes, discussed breakthrough pain generally and stated that [redacted]

400. Teva admitted, based on its "analysis of prescription data," that "many physicians have elected to prescribe [Actiq] to treat conditions outside" its labeled indication. In fact, some data showed that in the first half of 2006, only 1% of prescriptions for Actiq filled at retail pharmacies in the U.S. were written by oncologists. One internal presentation showed nearly [redacted]

401. Accordingly, Actiq became a huge money-maker for Teva, going from approximately $15 million in annual sales when Teva acquired it in 2000 to over $500 million by 2006.

402. In 2008, Cephalon ended up pleading guilty to federal criminal charges based on its off-label promotion of Actiq, admitting that between January and October 2001 it "promoted Actiq for uses not approved by the FDA, including for non-cancer pain uses, such as injuries and migraines." In a separate civil settlement executed contemporaneously with the plea agreement, Cephalon agreed to pay $375 million to resolve False Claims Act allegations on behalf of the United States and certain state Medicaid programs, including Illinois.

403. Although Fentora, like Actiq, was only approved for treatment of breakthrough pain in opioid-tolerant cancer patients, Teva's business plan for Fentora was, in large part, [redacted]

[redacted]

404. Specifically, it was the approximately 2,000 health care providers who were responsible for 80% of Actiq prescriptions that became the "primary target audience" for Fentora when it was launched. Teva's next priority, after high Actiq prescribers, was to target high prescribers of opioids generally, regardless of whether they treated patients with cancer pain.

405. Teva both in internal and external marketing materials, as well as through CMEs, commonly used the general term "breakthrough pain" rather than "breakthrough cancer pain" to promote off-label use of its drugs. Indeed, as part of a marketing push soon after the launch of Fentora, [redacted]

406. At a June 2007 sales meeting, Teva described the ideal Fentora patient as [redacted]

407. Teva's strategy continued to work. In June 2007 the company tracked that [redacted]

408. By September 2007, just a year after Fentora's approval, concerning reports of serious adverse events, including deaths, in patients taking Fentora prompted both a "dear healthcare professional" letter to be sent by Teva and a public health advisory to be issued by the FDA, warning healthcare professionals of the dangers of Fentora, including off-label prescribing. The FDA public health advisory makes clear that "deaths occurred in patients who did not have cancer and/or were not opioid tolerant."

409. Despite this, Teva pushed forward with its long-held plan of seeking FDA approval for a broader indication for Fentora for the management of non-cancer breakthrough pain, submitting its sNDA for an expanded indication in November 2007.

410. In February 2008, an internal audit of Teva's sales and marketing practices found that the company's marketing documents [redacted]

411. Teva's sNDA was denied in September 2008. The FDA's denial stated that Teva had "not adequately addressed the public health concern of increased abuse, misuse, overdose and addiction that is to be expected with more widespread availability of [Fentora] in the community."

412. Teva was undeterred by the FDA's decision, and its off-label marketing misconduct continued.

413. In March 2009, the FDA sent Teva a warning letter citing concerns over Teva's online marketing for Fentora. The letter addressed materials that failed to disclose the risks associated with the drug. The letter also addressed marketing that the FDA called "misleading" because it failed to convey the full indication for Fentora and instead dangerously suggested that "Fentora is appropriate for all cancer patients without breakthrough pain" instead of only opioid-tolerant cancer patients.

414. Teva found that [redacted]

415. Teva's marketing of Fentora off-label is further evidenced by the fact that, just like for Actiq, its sales representatives made regular and repeated Fentora sales calls on health care providers who were unlikely to treat cancer-related pain. Rather than focusing on oncologists and/or pain specialists who treated cancer-related pain, Teva directed its promotion and marketing, including in Illinois, to high-volume opioid prescribers in other specialties.

416. Between 2006 and 2016, Teva sales representatives made tens of thousands of Fentora sales calls to health care providers with specialties in Physical Medicine & Rehabilitation, Sports Medicine, Family Medicine, Emergency Medicine, Orthopedic Surgery and Rheumatology.

417. Teva sales representatives regularly detailed physicians in Illinois that they knew were not prescribing Fentora for cancer-related pain. For example, [redacted]

418. The same Illinois sales representative sent an explanation to his regional manager in March 2014 regarding his efforts to target certain physicians. [redacted] The Illinois sales representative noted [redacted] In the same document, the Illinois sales representative describes [redacted]

[redacted]

419. [redacted]

420. Throughout this time period, Teva also dedicated substantial resources to sponsoring "educational" efforts that encouraged off-label use of the drug. Teva itself has long identified its allocation of resources [redacted]

421. For example, Teva funded a 2006 CME titled "The Clinical Management of Breakthrough Pain: Current and Emerging Perspectives" which was [redacted] This CME discussed the similarities between cancer and noncancer pain and went on to tout the effectiveness of "rapid onset" opioids like Actiq and Fentora. This CME included some sample patient fact patterns and discussed and/or recommended the use of rapid-onset opioids for breakthrough pain in patients without cancer.

422. Teva sponsored a CME that was published in a supplement of Pain Medicine News in 2009 titled "Opioid-Based Management of Persistent and Breakthrough Pain." The CME told health care providers that "broad classification of pain syndromes as either cancer- or noncancer-related has limited utility." It also stated that while characteristics of breakthrough pain in

patients with cancer are "well described," that "similar prevalence, patterns, and functional effects have been observed in patients with such [chronic non-cancer pain] conditions as [osteoarthritis], neuropathic pain, and [lower back pain]" and discussed and encouraged the use of rapid-onset opioids, like Actiq and Fentora, for non-cancer breakthrough pain.

423. In December 2011, Teva funded a journal supplement titled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to *Anesthesiology News*, *Clinical Oncology News* and *Pain Medicine News*, publications sent to thousands of healthcare providers. This supplement contained detailed discussion of breakthrough pain in noncancer patients and supported the use of Teva's products to treat non-cancer breakthrough pain, stating that Fentora "has been shown to be effective in the treatment of BTP associated with multiple causes of pain."

424. The results of Teva's efforts were widespread use of Actiq and Fentora for off-label purposes and massive profits for Teva.

Teva misled providers and patients about the risk of opioid addiction

425. Early on, Teva identified [redacted]

Teva used branded and unbranded marketing to mislead health care providers and patients about the dangers of prescription opioids, particularly the risk of addiction.

426. As part of its launch of Fentora in 2006, [redacted]

[redacted]

427. This same deceptive statement also appeared directly on Teva's website for Fentora, Fentora.com.

428. Teva sponsored and helped develop a guidebook titled *Opioid Medications and REMS: A Patient's Guide*, which was both posted online and printed as a patient handout. This guide included misleading claims about addiction risk, telling the public that "[s]ome people are nervous about taking opioids because they are afraid they will become addicted. However, patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

429. One Teva document listed proposed answers to frequently asked questions about Actiq, including from patients. [redacted]

430. Teva's Actiq sales training materials taught its sales representatives, among other things, that [redacted] Similarly, an April 2014 sales training learning module for Fentora [redacted]

431. Teva's sales representatives misrepresented the risk of addiction when making sales calls to health care providers, including in Illinois. As an example, during a 2002 Actiq sales call, one Teva sales representative summarized her visit with an Illinois Internist as follows: [redacted]

[redacted]The same sales representative noted [redacted]

432. Teva similarly trained its speakers to deliver misleading messages as part of its speakers program. [redacted]

433. Teva also made misrepresentations in its managed care dossiers for its opioid products. These types of dossiers are created by drug manufacturers to present information regarding their drugs to managed care organizations, in order to gain formulary placement, coverage and reimbursement.

434. Between at least 2010 and 2011, Teva's Actiq managed care dossier told health plans that [redacted]

435. Teva funded various third-party publications and CMEs that similarly misled health care providers and patients about the risk of addiction with opioid treatment.

436. For instance, Teva helped fund the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which implied that addiction is limited to extreme cases of unauthorized dose

escalations, obtaining opioids from multiple sources, or theft. The guide talks about "confusion and hesitation" among providers and the public including over the concern "that the average person will become addicted to these drugs" and that those in pain need to make sure "myths and misunderstandings do not get in the way of effective pain control."

437. The *Treatment Options* guide also stated that "[d]espite the great benefits of opioids, they are often underused," and this "under-use has been responsible for much unnecessary suffering." It also emphasized that "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction."

438. Likewise, a Teva-sponsored CME titled "Advances in Pain Management" told health care providers that "opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."

439. Teva's understating of the risk of addiction was misleading and was meant to make providers more comfortable with prescribing opioids, and patients more comfortable with taking them.

Teva made deceptive claims about the extent to which addiction risk can be managed and addiction prevented

440. Teva also sought to reassure doctors that they could effectively manage any addiction risk in their patients by using abuse and diversion mitigation tools, even though there was not adequate evidence to support the effectiveness of such strategies.

441. Teva promoted the use of various screening tools, including through its funding of third parties and speaker programs, overstating the efficacy of these tools to prevent or mitigate the risk of abuse and addiction.

442. For instance, an abuse, addiction, and diversion slide deck titled "Pain Management: Understanding Opioids and Managing Their Risks" that Teva used as part of its speakers

program promoted the use of various screening tools. [redacted]

443. In 2008, Teva sponsored, [redacted] a CME titled "Utilizing Opioid Therapy for Chronic Pain: A Case-Based Approach to Optimize Therapeutic Outcomes While Managing Potential Risks" that had the goal of "[i]ncreasing personal confidence in utilizing opioid therapy for patients when appropriate." The CME similarly promoted the use of numerous screening and risk mitigation tools. As to one screening tool, the Screening Instrument for Substance Abuse Potential or SISAP, the CME stated that it would allow health care providers to "focus on the appropriate use of opioid analgesics...in the majority of patients who are not at risk of opioid abuse." It too promoted the use of the ORT, stating that although further research is needed, "[t]he ORT appears to be highly valid." These CME materials were made available to health care providers nationwide, including in Illinois, through the website www.pain.com.

444. In reality, as the 2016 CDC Guideline, and other sources, note, there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient agreements, or urine drug testing "for improving outcomes related to overdose, addiction, abuse, or misuse."[88]

Teva deceptively used terms like dependence, tolerance and "pseudoaddiction" to downplay the risk of addiction

[88] Dowell, *supra* note 15, at 22-24.

445. Teva further downplayed the problem of addiction by promoting the concept that signs of addiction are actually the result of untreated pain, which should be addressed by prescribing even more opioids.

446. A July 2006 Teva patient brochure titled "Making Pain Talk Painless" instructed patients to seek out more opioids, stating that "pseudoaddiction" is "[m]edicine-seeking behavior caused by not taking enough pain medicine and can be mistaken for addiction. This is NOT addiction. If you feel you are not taking enough medicine to relieve your pain, talk with your doctor." Teva disseminated this brochure in Illinois and nationwide, including by making it downloadable from Teva's website for Fentora, www.fentora.com.

447. Teva taught sales representatives that "pseudoaddiction" is a [redacted] According to Teva's training materials, healthcare professionals [redacted]

448. Teva's brochure titled "A Pain Primer: A reference for the rest of us," which was used for sales training, [redacted]

449. Teva also funded third-party groups and medical education to disseminate these deceptive claims.

450. Teva sponsored and disseminated the 2007 book *Responsible Opioid Prescribing* which warns doctors to "[b]e aware of the distinction between *pseudoaddiction* and addiction." (Emphasis in original). It explains that "[p]atients who are receiving an inadequate dose of opioid medication often 'seek' more pain medications to obtain pain relief," and "[t]his is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction."

451. The Teva-sponsored book lists examples of behaviors that are deemed "LESS indicative of addiction" including "hoard[ing] medications," "tak[ing] someone else's pain medications" and "us[ing] more opioids than recommended."

452. By comparison, the Teva-sponsored book identifies addiction-indicating behaviors as being much more extreme, including "[stealing] money to obtain drugs," "[p]erform[ing] sex for drugs," and "[p]rostitut[ing] others for money to obtain drugs."

453. Similarly, a 2008 Teva-sponsored CME titled "Advances in Pain Management" gave health care providers recommendations for making the "differential diagnosis" between addiction and pseudoaddiction. The CME said that addiction included "out-of-control behavior" by patients, while pseudoaddiction was "undertreated pain [that] leads to desperate acting out" including a patient "turn[ing] to alcohol, street drugs, or doctor shopping" and that these behaviors would subside once pain was adequately treated.

454. The 2016 CDC Guideline confirms the invalidity of the concept of "pseudoaddiction," advising that physicians should consider *discontinuing* opioid use for those patients who are exhibiting behaviors that indicate ineffective pain relief, not *increasing* their doses.[89]

[89]Dowell, *supra* note 15, at 2.

Teva misrepresented opioids' ability to improve function and quality of life

455. Despite the lack of evidence of improved function with long-term opioid use, Teva made deceptive and unsubstantiated claims regarding the improved quality of life and function resulting from opioids in general and its own opioid products in particular.

456. Teva sales representatives were trained to use and did use these deceptive claims when promoting Teva's opioid products.

457. For example, during Actiq sales calls with Illinois health care providers, Teva sales representatives noted discussing the following:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

and

e. [redacted]

458. This strategy continued with the marketing of Fentora. A 2007 Strategic Marketing Plan for Fentora identified [redacted]

459. In accordance with this strategy, the Teva-sponsored and -developed guide *Opioid Medications and REMS: A Patient's Guide* told consumers, among other things, that opioid medications can be highly effective for "improving functioning in many people," and that a

doctor would monitor them while taking opioids to ensure that "the benefits of opioid therapy (including improved quality of life) outweigh the risks."

460. Similarly, the book *Responsible Opioid Prescribing* (2007), which Teva sponsored and distributed, taught that "[o]pioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins." The first page of *Responsible Opioid Prescribing* states that patients "who rely on opioids for . . . improved function deserve access to safe and effective medication."

461. The Teva-sponsored CME titled "Advances in Pain Management" told health care providers that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function."

462. Teva made these claims without adequate substantiation to support them. Indeed, contrary to Teva's claims, the available evidence indicates opioids do not improve function or quality of life when taken long-term – indeed, they may harm patients' health.[90]

Teva deceptively pushed prescribers to increase opioid doses

463. Actiq is available in 200, 400, 600, 800, 1200 and 1600 mcg doses. Fentora is available in 100, 200, 400, 600 and 800 mcg doses. Taking just one Fentora 800 mcg tablet is equivalent to approximately 104 MMEs, which is already more than the 90 MME daily threshold recommended by the 2016 CDC Guideline. Patients may be taking Actiq or Fentora several times a day to treat multiple spikes in pain. Moreover, Actiq and Fentora are intended only for those patients who are opioid tolerant and therefore already being treated with around-the-clock opioids for their underlying persistent pain. Thus, patients taking Teva's products are likely already at a very high MME level per day.

[90] *See, e.g.*, Furlan et al., *supra* note 83; Dersh et al., *supra* note 75.

464. Teva's marketing for Actiq and Fentora emphasized the availability of multiple dosage strengths for flexible dosing.

465. Early on, Teva identified prescriber complaints surrounding what some considered a cumbersome titration process as a possible threat to its sales of Actiq. Rather than cautioning prescribers and patients about the dangers of increasingly higher opioid doses, Teva sought to encourage the use of higher dosage strengths more quickly.

466. A 2001 Actiq Marketing plan discusses [redacted] The FDA-approved prescribing information states that the appropriate initial dose of Actiq should be 200 mcg and that patients should be titrated step by step to the next higher available dose.

467. Concerned with prescriber complaints and the possible loss of sales, Teva's marketing plan stated that Teva [redacted] The presentation further discusses [redacted]

468. Teva also trained its sales representatives to emphasize to health care providers [redacted]

469. Similarly, Teva's website for Actiq, www.actiq.com, included a "How Do I Prescribe ACTIQ?" page that told prescribers that "[m]ost patients will require titration to a dose higher than the recommended starting dose" and included a chart showing that half of patients end up taking 800 mcg or higher doses.

470. Teva followed the same playbook when it came to Fentora. For example, 2010 Fentora sales training materials guided representatives [redacted]

471. Teva's reports prioritizing health care providers for detailing not only tracked the number of prescriptions each health care provider wrote, but also the breakdown of the strengths of Actiq and Fentora each health care provider was prescribing.

472. Teva pushed the use of higher doses of its products and also promoted the idea that there is no maximum or ceiling dose for its opioid products and opioids in general, including directly through sales calls and through third parties, again without disclosing the increased risks of taking higher doses of opioids.

473. For instance, a Teva sales representative discussed proper dosing of Actiq [redacted]

474. Another Teva sales representative called on an Illinois psychiatrist numerous times and [redacted] At one point, the Teva representative [redacted]

[redacted]

475. The Teva-sponsored APF publication, *Treatment Options: A Guide for People Living with Pain*, similarly minimizes addiction risk and claims that opioids have "no ceiling dose."

476. In reality, opioids are increasingly dangerous at higher doses. Higher opioid dosages are associated with increased risks, including an increased likelihood of death from opioid-related causes.[91]

Teva deceptively sought to keep patients on opioids for as long as possible, including by making deceptive statements about its long-term study of Fentora

477. Even though opioids are most dangerous when taken long-term and at higher doses, Teva sought to encourage health care providers to prescribe and patients to take its opioid products for as long as possible.

478. Teva relied on and understood that continued users of its opioid products were important to Teva's bottom line, noting in 2012, for instance, [redacted]

479. Between 2004 and 2007, Teva sponsored and conducted various clinical trials for Fentora. One study, which Teva commonly referred to as the "Weinstein" study after one of its co-authors, Dr. Sharon Weinstein, was an open-label, long-term study to assess "the long-term safety and tolerability of [Fentora] in opioid-tolerant patients with cancer and breakthrough pain."[92] The study results were published in June 2009 in the journal *Cancer*.

[91] Frieden, *supra* note 53.

[92] Fentanyl buccal tablet for the treatment of breakthrough pain in opioid-tolerant patients with chronic cancer pain: A long-term, open-label safety study. Weinstein SM, Messina J, Xie F. Cancer. 2009 Jun 1;115(11):2571-9. doi: 10.1002/cncr.24279. Erratum in: Cancer. 2009 Jul 15;115(14):3372.

480. The study aimed to follow participants over 12 months. However, given that the study involved patients with malignant cancer, many of the study participants died during the study, some in the first week.

481. Participants self-administered Fentora as needed for breakthrough pain episodes, recording in a diary the number of BTP episodes and the number of Fentora tablets taken each day.

482. Teva used the uncontrolled Weinstein study as a basis to make various deceptive claims about the long-term safety and efficacy of Fentora.

483. The Weinstein study itself concluded that Fentora was "generally well tolerated and had a favorable safety profile during the long-term treatment of BTP" and that the results "suggest[ed] there was no decline in analgesic efficacy over time in most patients."

484. [redacted]

485. Teva's claims were misleading because, in fact, only 34 of the 197 patients that began the 12-month maintenance portion of the study, or approximately 17%, actually finished the full 12 months or at least 360 days.

486. In addition, Teva ignored or downplayed the fact that many study patients were taking more and more doses of Fentora per day. Thus, even if each individual dispensed dose remained

the same strength, this meant many study participants' daily dose, or micrograms of Fentora per day, were increasing.

487. Furthermore, Teva downplayed the signs of misuse, abuse or addiction demonstrated by study patients, not including such behavior in adverse event listings and often categorizing the discontinuation of patients for these reasons as "Other."

488. Teva's deceptive and unsubstantiated claims about the study were used to persuade health care providers and patients, including in Illinois, that Teva's powerful and dangerous drug was appropriate for long-term use.

489. Teva also fueled sales of high doses and continued use of its opioid products through its various prescription savings programs, including voucher and co-pay assistance programs.

490. As of August 2013, Teva found that [redacted]

[redacted]

Teva deceptively compared the risks and benefits of its products and those of alternative forms of pain treatment

491. As another element of its marketing plan, Teva sponsored and distributed materials that made deceptive and/or unsubstantiated claims that other forms of pain treatment were more dangerous or less effective than they actually were, in order to encourage the use of opioid products generally and Teva's opioid products in particular.

492. Teva sponsored a 2005 publication co-authored by Dr. Scott Fishman titled *Consensus Panel Recommendations for the Assessment and Management of Breakthrough Pain* that, among other things, describes nonopioids such as acetaminophen or NSAIDs as less desirable treatments for breakthrough pain, including because of "dose-limiting toxicities," "onset of a half-hour or more," "concerns about cardiovascular morbidity" and "no published evidence…to

support their use in BTP," while concluding that oral transmucosal fentanyl citrate, or Actiq, is appropriate for most types of BTP. This publication is still available online.

493. Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some opioids differ from NSAIDs in that they have "no ceiling dose as there is with the NSAIDs" and are therefore the most appropriate treatment for severe pain. *Treatment Options* attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the true figure was closer to 3,200 at the time. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," but omitted any corresponding warning about the long-term risks of opioids.

Teva targeted its deceptive claims at senior citizens

494. Teva focused on marketing its opioids to the elderly.

495. Teva closely tracked coverage for its opioid products under Medicare Part D [redacted]

496. In a 2007 marketing plan for Fentora, Teva identified [redacted]. The same presentation later laid out Teva's public relations plan [redacted]

497. Teva targeted this population even though elderly patients are at higher risk for the most dangerous side effect of opioids—respiratory depression. They also are likely to experience more severe consequences from falls (fractures and hospitalizations) caused by the cognitive impairment that is associated with opioid use.

Teva used its speakers program to pay high-volume prescribers to prescribe Fentora

498. Teva officially described its speaker program as [redacted]

499. In reality, Teva often used the program to maintain positive relationships with high prescribers, rewarding and encouraging their prescribing of Fentora, including in Illinois, through speaker payments and expensive meals.

500. [redacted]

501. Many of the speaker events Teva held in Illinois were "venue based," taking place at upscale restaurants in the Chicago area, as opposed to in-office or via teleconference, for instance.

502. Teva reserved venue-based programs [redacted] Teva found that [redacted] The company also recognized [redacted]

503. At these events, in addition to their meal, Illinois speakers received honoraria [redacted]

504. Teva made many of the highest decile Illinois prescribers part of its speakers program, specifically paying them for "venue-based" programs.

505. As an example, an Illinois anesthesiologist [redacted] Between 2006 and 2009, this Illinois anesthesiologist

[redacted] Most of the events were at nice restaurants and often involved lavish food and beverage costs.

506. [redacted]

507. [redacted]

508. Internal correspondence from this same time period shows Teva evaluated the [redacted]

509. Teva also [redacted]

Teva used branded and unbranded marketing targeted at Illinois health care providers and patients to disseminate its misleading messages

510. Teva disseminated these deceptive and unfair messages directly to consumers and health care providers and indirectly through third-party front groups, KOLs and speakers programs.

511. Between 2006 and 2016, [redacted] In 2006 alone, [redacted]

512. One Teva sales representative who had responsibility for part of Chicago [redacted]

513. Teva focused its sales calls on high-prescribing physicians.

514. For example, one Illinois anesthesiologist [redacted]

515. Teva also used third-party pain advocacy groups, KOLs and its speakers programs to disseminate misrepresentations, including in Illinois.

516. In its 2007 public relations plan for Fentora, [redacted]

517. Teva recognized the importance of KOLs, citing in internal documents [redacted]

518. Included among the KOLs that received significant funding from Teva was Dr. Lynn Webster. Dr. Webster is the former President of AAPM. Among other things, Dr. Webster authored and/or served as faculty for various CMEs funded by Teva, including as part of the

Emerging Solutions in Pain Initiative. He published Teva-funded studies on the use of Actiq and Fentora for non-cancer pain. [redacted]

519. In 2004, Dr. Webster provided a written interview for posting to the website Pain.com, discussing a study he conducted about the use of Actiq for noncancer pain [redacted]

520. Teva provided financial support to various third-party groups, including AAPM, APS and APF. For example, [redacted]

521. Teva funded, referenced and/or disseminated materials, including treatment guidelines, from third-party groups, designed to look independent, which contained deceptive and misleading statements about opioids.

522. Teva also repeatedly detailed physicians who were ultimately arrested, convicted or received professional discipline for conduct related to their prescribing of controlled substances.

523. For example, Teva sales representatives [redacted] an Illinois neurologist who, in August 2013, was fined and placed on probation by IDFPR for excessive prescribing of controlled substances without considering warning signs of abuse. [redacted]

[redacted] In 2016, this physician's license was indefinitely suspended after the doctor failed to comply with the terms of IDFPR's probation.

524. As another example, Teva sales representatives [redacted] In January 2017, this pain specialist's license was placed on indefinite probation by IDFPR based on allegations that the doctor prescribed controlled substances for non-therapeutic purposes.

525. Teva sales representatives also regularly called on an Illinois anesthesiologist who was indicted in 2012 and later convicted on federal health insurance fraud charges. Teva reluctantly stopped calling on this doctor [redacted] This Illinois anesthesiologist was reprimanded and fined by IDFPR in April 2014 for issuing prescriptions without an Illinois Controlled Substance License.

Teva's unfair and deceptive marketing increased the sales of its generic opioid products

526. Teva was among the top five manufacturers of opioids supplied in Illinois between 2006 and 2012, selling tens of millions of opioids in the state. Teva's opioid business is fueled in large part by its significant generic opioids portfolio, which included generic versions of, among other drugs, OxyContin, Opana, and MS Contin.

527. Teva also purchased and now sells generic opioids through the former generic opioids unit of Allergan and assumed liabilities for conduct related to the generic opioids business it purchased.

528. Teva's efforts in support of its branded drugs, as well as Teva's unbranded marketing, inevitably impacted sales of generic opioids which Teva knew health care providers would frequently prescribe or dispense in place of branded products.

529. Through its unfair and misleading marketing, Teva sought to expand overall demand for these dangerous drugs, fueling abnormally high levels of opioid prescribing and unprecedented levels of diversion, addiction, and death.

Allergan

530. Allergan has engaged in numerous deceptive and unfair acts and practices designed to push opioids for long-term use at high doses, all to increase its sales of opioids. Allergan accomplished this by (1) misleading providers and patients about the risk of addiction to opioids and the extent to which the risk of addiction could be managed and prevented; (2) misrepresenting opioids' ability to improve function and quality of life: (3) deceptively pushing prescribers to increase opioid doses and lengths of opioid therapy for their patients; and (4) deceptively comparing the risks and benefits of its opioid products with those of competing opioids and alternative forms of pain treatment. Allergan did this despite the lack of evidence that opioids improve patients' quality of life and function long-term and despite the well-documented risks of its drugs.

Allergan misled providers and patients about the risk of opioid addiction

531. Allergan misled health care providers and patients about the adverse effects of opioids, particularly the risk of addiction. Allergan deceptively promoted the concept of "pseudoaddiction" and deceptively claimed that abuse-deterrent features of its products minimized the risk of addiction.

532. Allergan deceptively used terms like dependence, tolerance and "pseudoaddiction" to downplay the risk of addiction.

533. "Pseudoaddiction" was meant to differentiate between "undertreated pain" and "true addiction" – as if the two were mutually exclusive. According to the concept of

"pseudoaddiction," the signs of addiction are actually the product of untreated pain, which should be treated by prescribing even more opioids.

534. Allergan promoted the idea of "pseudoaddiction" even though there was no competent scientific evidence supporting this concept.

535. Allergan's sales representative training was especially problematic. After Allergan acquired the rights to sell Kadian from Alpharma, [redacted]

536. Through its *"Kadian Learning System,"* Allergan trained its sales force to deceptively minimize the risk of addiction. Specifically, Allergan attributed addiction to predisposing factors such as family history of addiction or psychiatric disorders, emphasized the difference between substance dependence and substance abuse, and promoted the term "pseudoaddiction."

537. The [redacted] instructed sales representatives [redacted]

538. In truth, the CDC has explained that "patients who do not experience clinically meaningful pain relief early in treatment (i.e. within 1 month) are unlikely to experience pain relief with longer-term use,"[93] thus advising that physicians should consider *discontinuing* opioid use for those patients who are exhibiting behaviors that indicate ineffective pain relief, not *increasing* their doses.

[93]Dowell, *supra* note 15, at 2.

539. Allergan informed its sales force that tolerance and dependence do not indicate addiction; rather, they are expected consequences of opioid use over a length of time, and rarely prevent effective pain relief.

540. Allergan's training materials included statements such as: [redacted]

541. Allergan's training presentation, [redacted]

542. Allergan trained its sales representatives to [redacted]

543. Allergan's sales representatives were taught [redacted]

544. Allergan's "*Learn more about customized pain control with Kadian*" patient material represented that addiction to morphine-based drugs like Kadian is less likely for patients who have never had an addiction problem. The piece goes on to advise patients that a need for a dose

adjustment is the result of tolerance rather than addiction, which strongly suggests that the overall risk of addiction was minimal.

545. Contrary to Allergan's representations, up to 26% of opioid users in primary care settings and as many as 30% or even 40% of long-term opioid users experience problems with addiction. Allergan's representations that the risk of addiction is low were misleading.

546. Furthermore, in practice, opioids are all too often prescribed by providers for patients at serious risk for addiction or who are already addicted to opioids – often at high doses.[94]

547. Allergan misrepresented the abuse potential of its opioid products, specifically by claiming that Kadian had abuse-deterrent properties.

548. Abuse-deterrent formulations were designed to make opioid pills harder to crush, dissolve, or otherwise manipulate; however, most prescription opioids that are abused are swallowed whole, and oral ingestion is equally risky. In fact, studies suggest that only about 10% to 20% of all opioid users snort or inject pills; there is no evidence that orally-administered opioids are less addictive.[95]

549. The CDC also observed that abuse-deterrent technologies do not prevent overdose through oral intake.[96] The 2016 CDC Guideline found no evidence or studies to support the notion that abuse-deterrent formulations have any effectiveness as a risk mitigation strategy for deterring or preventing abuse.[97]

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[94] Karen H. Seal, *et al.*, *Association of Mental Health Disorders With Prescription Opioid and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan,* 307 J. Am. Med. Ass'n 940 (2012).
[95] Catherine S. Hwang *et al.*, *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion,* 32 Clinical J. Pain 279 (2016).
[96] Dowell, *supra* note 15, at 2.
[97] *Id.*

550. Kadian never received FDA approval as an abuse-deterrent formulation, but that did not stop Allergan from deceptively representing that Kadian is more difficult to abuse and less addictive than other opioids.

551. Specifically, Allergan's [redacted] which was a resource used by Allergan to answer health care provider inquiries, stated that [redacted]

552. These statements convey that Kadian does not cause euphoria and therefore is less addictive and that Kadian is less prone to tampering and abuse, even though such claims had no substantial clinical evidence to support them and were not approved by the FDA.

Allergan misled providers and patients about the extent to which the risk of addiction could be managed and prevented

553. Allergan dedicated resources to develop a sophisticated campaign to help health care providers feel comfortable prescribing highly addictive opioids.

554. Convincing prescribers that they could effectively manage the risk of and prevent addiction was essential to Allergan's marketing strategy of increasing the number of opioid prescriptions generally and its own branded drugs in particular.

555. Allergan downplayed the difficult and painful effects that many patients experience when dosages are lowered or opioids are discontinued, and which decrease the likelihood that those patients will be able to stop using opioids.

556. For example, both Allergan's [redacted]

557. [redacted]

558. Allergan's promotional materials for Kadian also [redacted]

559. Allergan also deceptively claimed that opioid treatment for patients with a high risk for abuse and addiction [redacted]

560. For example, [redacted]

561. [redacted]

562. Allergan sales representatives were instructed to [redacted] when addressing the potential for abuse in the treatment of chronic pain with opioids.

563. However, a 2014 report by the Agency for Healthcare Research and Quality "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" and identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[98]

564. Similarly, the evidence shows that methods for preventing abuse and addiction, such as patient contracts, more frequent refills, and urine drug screening, often do not work when prescribing opioids to high-risk patients.[99]

565. Indeed, the 2016 CDC Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient agreements, urine drug testing or pill counts "for improving outcomes related to overdose, addiction, abuse, or misuse."[100]

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

[99] Michael Von Korff *et al., Long-Term Opioid Therapy Reconsidered,* 155 Annals of Internal Med. 325 (2011); Laxmaiah Manchikanti *et al., American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1 – evidence Assessment,* 15 Pain Physician S1 (2012).

[100] Dowell, *supra* note 15, at 11.

Allergan misrepresented opioids' ability to improve function and quality of life

566. Allergan made deceptive and unsubstantiated claims regarding the improved quality of life and function resulting from opioids in general and its own drugs in particular.

567. Opioids may initially improve function by providing pain relief in the short term, but there is no evidence that opioids improve patients' function in the long term.

568. Despite the lack of evidence of improved function long term, Allergan deceptively promoted opioids as improving function and quality of life without disclosing the lack of evidence for this claim.

569. Promotional materials for Kadian prior to February 2010, including its Co-Pay Assistance Promotional brochure and its comparison detailer, advertised that the use of Kadian to treat chronic pain would allow patients to return to work, relieve stress on the body and on mental health, and cause patients to enjoy their lives.

570. Allergan trained its sales representatives to emphasize that Kadian offered patients better pain control and sleep scores. Allergan touted that Kadian improved patient sleep scores in its comparison detailer; however, the study to which it referred was unpublished, and did not even support the conclusion that Kadian reduced the interference of pain on a patient's sleep.

571. In February 2010, the FDA warned Allergan that the claims made in its Kadian promotional materials were misleading, and that there was insufficient evidence to show that Kadian results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life.

572. Despite the FDA warning letter, Allergan persisted in training its sales force to [redacted]

[redacted]

573. [redacted]

574. Allergan's claims that opioids improve function and quality of life long-term are deceptive. There is no evidence supporting these claims; in fact, the evidence shows the claims are untrue.

Allergan deceptively pushed prescribers to increase opioid doses

575. Allergan used deceptive marketing materials to convince prescribers that escalating opioid dosage was safe for patients. This was critical to Allergan's efforts to market opioids for long-term use to treat chronic pain because health care providers may not have chosen to initiate opioid therapy at all if they did not feel comfortable prescribing increasingly higher doses of opioids to counter their patients' building of tolerance to the drugs' effects.

576. [redacted]

577. Similarly, [redacted]

[redacted]

578. In 2012, as new dosage strengths of Kadian were becoming available, [redacted]

579. In reality and contrary to Allergan's claims, opioids are increasingly dangerous at higher doses. While 1 in every 550 patients on opioid treatment dies of opioid-related causes, that number increases to a staggering 1 in 32 for patients receiving 200 MMEs per day.[101]

580. In a national sample of Veterans Health Administration patients with chronic pain receiving opioids from 2004-2009, patients who died of opioid overdose were prescribed an average of 98 MME per day, while patients who did not were prescribed an average of 48 MME per day.[102]

581. Overall, evidence has shown higher opioid dosages to be associated with increased risks of motor vehicle injury, opioid use disorder, and overdose, and that the increased risk rises in a dose-dependent manner.[103]

Allergan deceptively sought to keep patients on opioids for as long as possible

582. Allergan's misrepresentations regarding the risk of addiction, the signs of addiction, the ability of opioids to improve function and quality of life, and the safety of higher doses of opioids were all part of the bigger picture of keeping patients on Allergan's opioid products for longer and longer periods of time.

[101] Frieden, *supra* note 53.
[102] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf (Last accessed September 9, 2019).
[103] Dowell, *supra* note 15, at 22-24.

583. Allergan's "KADIAN® Co-Pay Assistance Program" was one method through which it was able to increase the number of long term opioid users. In fact, the only objectives of the program [redacted]

584. Allergan's internal presentations and data showed that [redacted]

[redacted]

585. Allergan took advantage of [redacted]

Allergan deceptively compared the risks and benefits of its products and those of competing opioids and alternative forms of pain treatment

586. As another element of its marketing plan, Allergan made deceptive and/or unsubstantiated claims that competing products were more dangerous than they actually were, less effective than they actually were, or that Allergan's products were equivalent to or superior to competing opioids and nonopioids.

587. In spite of this, Allergan presented misleading comparisons between the risks and benefits of its extended-release opioid products and those of competing opioids and other nonopioid pain treatment methods.

Allergan's deceptive comparisons between its products and other opioids

588. Allergan made deceptive claims about its products as compared to other opioids, including that Allergan's opioid products were safer, more convenient for patients, and offered easier titration than competing opioids.

589. Allergan trained its sales force to promote Kadian as having no dose ceiling, [redacted]

[redacted]

590. [redacted]

591. [redacted]

592. Allergan promoted Kadian as being superior to its competitors by referring to [redacted]

Allergan's deceptive comparison between its products and alternative forms of pain treatment

593. Allergan's sales trainings, presentations, and promotional materials represented that opioids are superior to NSAIDs and acetaminophen to treat pain.

594. A July 2010 internal document on Kadian trained Allergan's sales force that NSAIDs can contribute to bleeding complications and have toxic effects on the kidney, and that the potential toxicity of NSAIDs limits their doses and duration of therapy. The training module's corresponding sections relating to opioids omit specifics of the risks or adverse side effects associated with opioid use.

595. [redacted]

[redacted]

596. Allergan's strategy worked, and opioids replaced other, safer options in health care providers' pain treatment repertoires. For example, a study of 7.8 million doctor visits between 2000 and 2010 found that while prescriptions for NSAIDs and acetaminophen fell from 38% to 29%, opioid prescriptions increased from 11.3% to 19.6%, driven primarily by the decline in NSAID prescribing.[104]

Allergan targeted high opioid prescribers in order to increase sales

597. Allergan's marketing strategy consistently focused on targeting the top prescribers of its opioid products. For instance, in preparation for the launch of its generic version of Opana ER, [redacted]

598. In 2012, Allergan developed new target lists [redacted] According to internal correspondence, Allergan [redacted]

599. Allergan's target lists included Illinois prescribers who were ultimately arrested, convicted or received professional discipline for conduct related to their prescribing of controlled substances. For example, a Gurnee, Illinois internist, [redacted], had his controlled substance license indefinitely suspended for failing to properly prescribe controlled substances to patients of his practice.

[104]Daubresse, *supra* note 81; *see also* John N. Mafi *et al.*, *Worsening Trends in the Management and Treatment of Back Pain*, 173 J. Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

Allergan used the benefit of its deceptive messages to drive its generic opioids business

600. Prior to the sale of its generic business to Teva, Allergan's marketing strategy included [redacted]

601. In fact, Allergan's detailing sales force was instructed to [redacted]

602. Allergan's sales representatives [redacted]

603. Allergan also promoted generic Opana ER. When Endo discontinued certain dosages of Opana ER, Allergan seized on the opportunity to increase its profits by [redacted]

604. Allergan rewarded its sales teams [redacted]

605. Allergan's promotion of its generic opioid products extended to direct mail campaigns, email campaigns, telemarketing efforts, and journal advertising.

606. For example, Allergan advertised its generic Opana ER [redacted]

607. In addition, Allergan aggressively marketed its generic opioid products through its distributors [redacted]

608. To promote Allergan's generic Opana ER, generic oxycodone, and generic Kadian, [redacted]

609. Allergan similarly collaborated with [redacted]

610. Allergan also worked [redacted]

611. Allergan's efforts in support of its branded drugs and the opioid market in general inevitably impacted sales of generic opioids which Allergan knew health care providers would frequently prescribe or dispense in place of branded products.

612. Through its unfair and misleading marketing, Allergan sought to expand overall demand for these dangerous drugs, fueling abnormally high levels of opioid prescribing and unprecedented levels of diversion, addiction, and death.

B. Distributor Defendants

613. The Distributor Defendants flooded Illinois with over one billion dosage units of dangerous opioids between 2006 and 2014. This inundation fueled the diversion of these drugs towards unlawful and harmful uses.

614. Despite their unique and crucial role as gatekeepers in preventing the diversion of opioids, the Distributor Defendants allowed and even enabled diversion on a massive scale, creating an opioid epidemic which has claimed the lives of thousands of Illinois citizens.

615. The Distributor Defendants were repeatedly instructed and warned regarding their responsibilities in safeguarding against the enormous public health hazard of opioid overuse, abuse, and addiction.

616. However, the Distributor Defendants prioritized profits over the health and general welfare of Illinois citizens, and failed to meet their obligations to implement effective compliance policies to stem the flow of addictive drugs into the State.

The Distributor Defendants' Role in the Distribution of Opioids

617. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distributors, like the Distributor Defendants. The Distributor Defendants then supply opioids to retail pharmacies, hospitals, nursing homes, and other healthcare providers, which then dispense the drugs to pharmacy customers.

618. The Distributor Defendants are considered the "Big Three" of pharmaceutical distributors and together dominate 85% of the market share for the distribution of prescription opioids. Each of the Distributor Defendants is a Fortune 500 corporation listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription

drugs. Each has also been investigated and fined by the Drug Enforcement Administration ("DEA") or other governmental entities for the failure to meet state and federal standards regarding the distribution and control of drugs.

619. At all relevant times, the Distributor Defendants purchased opioids from manufacturers and sold them to retailers throughout Illinois.

Regulations Regarding the Distribution of Opioids

620. Because they are potentially harmful, prescription opioids are heavily regulated by federal and state authorities. For decades, opioids have been regulated both nationwide under the Controlled Substances Act, 21 U.S.C. § 801 et seq. ("CSA"), and in this State under the Illinois Controlled Substances Act, 720 ILCS 570/100, *et seq.*, and the Illinois Wholesale Drug Distribution Licensing Act, 225 ILCS 120/1, *et seq.*[105] These laws create a "closed system" that imposes obligations on everyone involved in the supply chain for controlled substances, including manufacturers and distributors, to prevent opioid diversion.

621. Diversion occurs whenever the supply chain of prescription opioids is broken and drugs are transferred from a legitimate channel of distribution or use to an illicit one. For example, at the distributor level, diversion may occur whenever opioid distributors fill suspicious orders from retailers. Diversion also occurs when distributors allow opioids to be lost or stolen in transit.

622. To prevent diversion, federal and state laws require wholesale distributors of prescription opioids to maintain effective controls over their prescription opioid supply chains and to maintain systems to monitor, identify, report, and suspend suspicious prescription opioid orders.

[105] This lawsuit does not seek to enforce or make a claim under any federal statute or regulation.

623. Federal law requires that the Distributor Defendants maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). Similarly, Illinois law provides that opioid distributors "shall maintain adequate security and provide effective controls and procedures to guard against theft and diversion . . . ." 720 ILCS 570/201; *see also* 225 ILCS 120/55(a)(16).

624. Distributors are required to have a system in place to identify any "suspicious orders" of opioids and other controlled substances. "Suspicious orders" include those "of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

625. The Distributor Defendants must stop shipment of any order flagged as suspicious. *See* 21 U.S.C. § 823(b) (requiring distributors to "maint[ain] effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels"). A distributor may ship the order only after due diligence has allowed it to determine that the order is not likely to be diverted.

626. The CSA also created an automated drug reporting system that monitors the distribution, shipment by shipment, of the opioids as well as other controlled substances ("ARCOS"). The Distributor Defendants and all others who are registered to distribute controlled substances must report acquisition and distribution transactions to the DEA through ARCOS. 21 U.S.C. § 827(d)(1); 21 C.F.R. §§ 1304.33(d), (e). A distributor that discovers a "suspicious order" must inform the DEA. 21 C.F.R. § 1301.74(b).

627. Each distributor must maintain a complete and accurate record of each substance manufactured, sold, delivered, or otherwise disposed of. 21 U.S.C. § 827(a)(3); 21 U.S.C. §§ 1304.21(a), 1304.22(b).

628. Under Illinois law, licensed wholesale drug distributors must exercise "good faith," which means dispensing controlled substances for conditions "other than that individual's physical or psychological dependence upon or addiction to a controlled substance" and considering the following factors: "(1) lack of consistency of prescriber-patient relationship, (2) frequency of prescriptions for same drug by one prescriber for large numbers of patients, (3) quantities beyond those normally prescribed, (4) unusual dosages (recognizing that there may be clinical circumstances where more or less than the usual dose may be used legitimately), (5) unusual geographic distances between patient, pharmacist and prescriber, [and] (6) consistent prescribing of habit-forming drugs." 720 ILCS 570/102(u); *see also* 225 ILCS 120/55(a)(4).

629. Illinois laws and regulations require each of the Distributor Defendants to maintain a complete and accurate record or "pedigree" of each opioid distribution with information including, but not limited to, the size, date, and destination of each shipment. 225 ILCS 120/57.

630. The Distributor Defendants also have common-law obligations in distributing these dangerous drugs, including a duty to not create a public nuisance by unreasonably interfering with the public health, safety, peace, and comfort as a result of these dangerous drugs making their way into the hands of drug dealers and addicts.

The Defendants Received Specific Guidance From The DEA Regarding Their Duties

631. In addition to the federal and state laws and regulations regarding controlled substances, Defendants received detailed, specific instructions from the DEA for identifying and minimizing the risk of opioid diversion in their supply chains by identifying any suspicious orders.

632. On September 27, 2006, the DEA Office of Diversion Control sent letters to all registered distributors – including Defendants – providing guidance on suspicious order monitoring of controlled substances and the Defendants' responsibilities and obligations to conduct due

diligence on controlled substance customers as part of a program to maintain effective controls against diversion (the "September 2006 DEA Letter").

633. The September 2006 DEA Letter reiterated that the Distributor Defendants are:

> one of the key components of the distribution chain. If the closed system is to function properly distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.

634. The September 2006 DEA Letter also reminded the Distributor Defendants that they have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." It explained that each distributor is required to exercise due care in confirming the legitimacy of all orders. The DEA also warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

635. The DEA described in its letter specific circumstances that could indicate diversion, including orders containing:

a. excessive quantities of a limited variety of controlled substances while ordering few if any other drugs;

b. a disproportionate ratio of controlled substances to non-controlled prescription drugs;

c. excessive quantities of a limited variety of controlled substances in combination with certain other drugs; and

d. the same controlled substance being ordered from multiple distributors.

636. On December 27, 2007, the DEA sent a second letter to wholesale distributors – including Defendants – reminding them of their statutory and regulatory duties to "maintain effective controls against diversion" (the "December 2007 DEA Letter").

637. The December 2007 DEA Letter advised the Distributor Defendants that they must perform an independent analysis of a suspicious order prior to completing the sale to determine if the controlled substances would likely be diverted, and that filling a suspicious order and then completing the sale absent this independent analysis violates their legal responsibility.

638. The December 2007 DEA Letter provided additional details and examples regarding when orders should be considered "suspicious," including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency." It made clear that "[t]hese criteria are disjunctive and are not all inclusive." Thus, "if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious."

639. The December 2007 DEA Letter also warned that wholesale distributors which "rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders." The DEA explained that:

> [A] system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

640. The December 2007 DEA Letter warned that "registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted . . . may be failing to maintain effective controls against diversion."

641. Lastly, the December 2007 DEA Letter stated that "[f]ailure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C.

§§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration."

642. Failing to adequately monitor and stop suspicious orders of controlled substances, thus allowing the illegal flow of these drugs, affects the health and general welfare of the public and is against the public's interest.

643. State and federal requirements make clear that, because of the Distributor Defendants' position within the distribution chain and their required level of knowledge, skill, and sophistication, they have a unique duty to maintain effective controls over controlled substances to prevent their abuse and diversion for illicit purposes.

644. The Distributor Defendants not only acknowledged that they understood their duties under the law, they publicly portrayed themselves as fully complying with those obligations and doing all they could to prevent diversion of opioids.

645. For example, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

646. Cardinal likewise claimed to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."

647. AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances."

648. However, despite these public representations and their clear duty, the Distributor Defendants have consistently failed to fulfill their obligations, leading to prescription opioids being diverted from the legitimate supply chain to illegitimate channels of distribution and illegal, non-medical use.

649. The Distributor Defendants have supplied and continue to supply quantities of prescription opioids in and around Illinois without taking proper measures based on their actual or constructive knowledge that individuals were consuming opioids for non-medical purposes. The Distributor Defendants should have stopped or investigated any shipment orders of unusual size, orders deviating substantially from a normal pattern, or orders of an unusual frequency, but they have unlawfully failed to do so.

McKesson

650. McKesson's written policies for compliance are memorialized in various iterations of its Controlled Substance Monitoring Program ("CSMP"), which applies to McKesson's operating and sales departments.

651. However, the flaws in McKesson's CSMPs have enabled the diversion of opioids throughout the country, including in Illinois.

652. McKesson's CSMP was ultimately deficient in numerous ways, rendering it substantially ineffective. For example, at various points the CSMP: (1) directed that customers' monthly threshold limits be set by reference to customers' prior ordering volumes, without requiring investigation of those volumes' appropriateness, effectively setting limits that incorporated prior unmitigated diversion; (2) failed to require key indicators of diversion as part of the company's due diligence of pharmacies, including but not limited to obtaining prescriber-level information; (3) alerted customers when they were nearing their monthly threshold limit for opioid products;

(4) failed to adequately design and operate a system to disclose suspicious orders to the DEA; and (5) required little to no diligence on chain pharmacy orders, so as to maintain these large customer accounts regardless of the consequences.

653. McKesson's threshold limits were set at inappropriately low levels. A former McKesson Director of Regulatory Affairs stated in internal correspondence from August 2011 that there were "large gaps between the amount of Oxy or Hydro" pharmacies were "allowed to buy (their threshold) and the amount they really need. (Their current purchases) This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be being used for legitimate purchases."

654. McKesson also vastly under-resourced its compliance department, assigned unqualified and untrained personnel to implement anti-diversion policies, routinely ignored its own policies, and otherwise failed to take reasonable steps to prevent diversion.

655. McKesson's lack of attention to its compliance and anti-diversion obligations is evidenced by the minimal resources the company invested in regulatory staff. Implementation of CSMP for all McKesson pharmacy customers across the country was left to a small number of regional Directors of Regulatory Affairs ("DRAs"). Each of the DRAs was responsible for onboarding new pharmacy customers, reviewing and increasing thresholds, and conducting all due diligence for all of the pharmacies across their region.

656. McKesson provided minimal training to its operations, administrative, and sales personnel with respect to their roles in ensuring the company's compliance with state and federal controlled substances laws and regulations.

657. McKesson also tasked sales staff with front-line compliance duties without providing adequate mechanisms to ensure that these employees' responsibilities and incentives to promote

sales did not compromise their ability or willingness to perform their compliance-related functions, when doing so could result in the loss of those sales.

658. McKesson's under-resourced, under-qualified, and untrained staff routinely bypassed critical procedures set forth in the CSMP and frequently failed to obtain and maintain the records called for by its CSMP in the due diligence files of its customers.

659. When customers requested increases in their threshold allowance for opioid orders, McKesson routinely approved those increases within days, hours, or even minutes, before any independent, diligent investigation could possibly have been conducted, and without being provided any reasonable justification.

660. On many occasions McKesson uncritically and immediately accepted the most perfunctory explanations from its customers. Internal correspondence reflects that, as of 2011, McKesson had "gotten to a point where" some threshold increases were "almost automatic" and that it "too easily accept[ed]" perfunctory reasons for increases. [redacted]

661. McKesson also treated national retail chains, which were a large source of business, more favorably than independent and small to medium chains. McKesson often abbreviated the threshold change request process for a pharmacy if it was a part of a national retail chain.

662. For example, [redacted]

663. In a January 2009 policy entitled "CVS CSMP: Threshold Review," McKesson directed its employees to approve automatic threshold increases for CVS "without further CVS

explanation," and to only seek justification for increases deemed "extraordinary" in order to "minimize disruption of business."

664. When McKesson did actually conduct additional searching and due diligence investigations beyond the perfunctory steps discussed above, it routinely failed to identify obvious red flags of diversion.

665. Finally, even when McKesson actually did identify customers' obvious red flags, it frequently failed to implement suspensions or terminations of its business transactions with those customers.

666. In many of these cases, instead of suspending or terminating these pharmacies, McKesson continued to supply them with high volumes of opioids, sometimes for years after the risk of diversion they posed should have been obvious.

667. McKesson's failure to conduct adequate due diligence and suspend or terminate suspicious orders included Illinois pharmacies. [redacted]

668. [redacted]

669. [redacted]

[redacted]

670. [redacted]

671. [redacted]

672. [redacted]

673. [redacted]

674. [redacted]

675. [redacted]

Cardinal

676. Prior to 2008, Cardinal did not have a formal system for detecting suspicious orders and relied on a failure-prone "manual process" for identifying problematic orders.

677. Cardinal's written policies for compliance were and are contained in "Standard Operating Procedures" that apply to its various operating and sales departments. These procedures were first implemented in December 2008 and have since undergone multiple revisions.

678. However, the flaws in Cardinal's policies have enabled the diversion of opioids throughout the country, including in Illinois.

679. Cardinal's policies were fundamentally flawed in that employees governed by one policy were unaware of the obligations imposed by other policies on other employees, even when effective anti-diversion measures required coordination. Furthermore, these policies are not readily available even to the employees charged with implementing them.

680. In addition, Cardinal's procedures and policies contained numerous gaps that would have prevented them from effectively preventing diversion, even if enforced. For example, these policies allowed onboarding of accounts even where customers failed to provide requested information about other suppliers, dispensing data, and top prescriber information.

681. Cardinal failed to employ sufficiently qualified compliance staff to implement these policies, failed to adequately train those compliance staff or its sales representatives concerning Cardinal's anti-diversion duties, and failed to enforce even the defective policies it had in place.

682. Cardinal failed to install qualified personnel in key compliance positions. For example, Cardinal's front-line "New Account Specialists" and "Analysts," responsible for onboarding new customers and monitoring existing customers, respectively, were sometimes recruited from the company's existing pool of administrative assistants. These employees, who had no experience in regulatory compliance, were generally supervised by pharmacists or other professionals with no prior experience in supervising investigative functions.

683. Moreover, Cardinal failed to provide adequate training to either these unqualified compliance personnel or sales representatives. Due to the lack of proper training and clear guidelines, compliance staff did not fully understand critical components of their jobs.

684. Unsurprisingly, these unqualified and untrained staff routinely failed to follow basic compliance procedures.

685. As to existing customers, Cardinal routinely failed to follow its own procedures for detecting, monitoring, and reporting suspicious orders. For one, Cardinal's compliance staff routinely released orders in excess of a customer's threshold without conducting the follow-up investigation and providing the detailed written justification called for by Cardinal's policies.

686. In a 2010 email among Cardinal employees about CVS orders being held, one employee wrote, "I spoke with Brian Whalen at CVS a couple of times this morning… They will not provide the doctor or patient information you requested unless it is requested by the DEA. He was quite adamant about this." Despite CVS's refusal, Cardinal released CVS's pending orders anyway. In fact, according to Cardinal's contract with CVS, CVS retained discretion to set its own threshold quantities for controlled substances at any level it deemed appropriate.

687. Even where Cardinal did block customers' orders and report them as suspicious to the DEA, it routinely took no steps to suspend or terminate those customers pending further

investigation, and instead allowed them to continue receiving their threshold amount of opioids month after month thereafter, regardless of whether the customer continued to make additional suspicious orders.

688. According to Cardinal's Vice President of Quality and Regulatory Affairs, suspicious order reports were not even reviewed until *after* the order had already been released to the ordering pharmacy.

689. Cardinal routinely continued to supply pharmacies that filled prescriptions for prescribers that had been flagged in its own infrequent investigations as likely sources of diversion.

690. Cardinal's failure to conduct adequate due diligence and suspend or terminate suspicious orders included Illinois pharmacies. [redacted]

691. [redacted]

692. [redacted]

693. [redacted]

694. Despite knowing of the broad failures of its compliance policies, both as written and as actually enforced, and knowing of numerous instances in which those failures had led to the company improperly distributing opioids in Illinois and other states, Cardinal never took meaningful steps toward adjusting its program to better prevent diversion.

AmerisourceBergen

695. AmerisourceBergen's compliance policies consist of its Diversion Control Program and its Order Monitoring Program ("OMP"). The programs are administered by AmerisourceBergen's Corporate Security and Regulatory Affairs ("CSRA") staff.

696. The flaws in AmerisourceBergen's policies have enabled the diversion of opioids throughout the country, including in Illinois.

697. For example, AmerisourceBergen's policies are flawed from the point of initial new customer onboarding. Since 2007, AmerisourceBergen has generally required as part of its new customer due diligence process a customer questionnaire, a site visit, license verification, and online investigation. A central component of AmerisourceBergen's new customer procedure is its Retail Pharmacy Questionnaire ("590 Form").

698. The 590 Form asks for information about other distributors, disciplinary history, customer payment methods, percentages of controlled substances, usage numbers for specific high-risk drugs, and top prescribers of opioids, among other questions.

699. AmerisourceBergen's onboarding process relies heavily on the customer's 590 Form, given that AmerisourceBergen requests dispensing information from new customers only when it already knows of potential issues.

700. However, despite the 590 Form being so critical to understanding its customers and ensuring it can fulfill its regulatory obligations, and despite numerous other AmerisourceBergen procedures relying on reviewing or updating this form, AmerisourceBergen often failed to adequately perform even this baseline screening.

701. For example, AmerisourceBergen did not require new customers to provide dispensing data as part of the onboarding process, and retail chain pharmacies were exempted from the 590 Form process.

702. AmerisourceBergen also allowed for frequent threshold manipulations so that its customers could avoid orders being held for review, rejected from shipment, or reported as suspicious. At least one of AmerisourceBergen's distribution centers was permitted to release orders that exceeded threshold limits as long as they did not exceed the threshold by more than 10%.

703. In many instances, high-risk orders that should have been held for review, rejected from shipment, or reported as suspicious were released in error.

704. Even when AmerisourceBergen actually did identify customers' obvious red flags and hold some orders for review, it frequently failed to conduct sufficient due diligence to determine whether the accounts were high-risk and failed to implement suspensions or terminations of high-risk accounts.

705. In some of these cases, instead of suspending or terminating these pharmacies, AmerisourceBergen continued to supply them with high volumes of opioids well after the risk of diversion they posed should have been obvious.

706. AmerisourceBergen also failed to employ sufficient numbers of qualified, adequately trained compliance staff to implement these policies and failed to ensure that those compliance staff were meeting AmerisourceBergen's anti-diversion duties.

707. In August of 2015, an audit conducted to review AmerisourceBergen's OMP found deficiencies including a lack of resources, lack of formal training, employees who felt overburdened by their workload and administrative demands, inconsistent policies, and communications breakdowns. Even though "regulatory obligations related to diversion control" were among the "Gaps & Risks" identified in the audit, AmerisourceBergen took no action, and made no changes, in response to the report.

The Distributor Defendants' compliance failures led to numerous enforcement actions against them

708. The Distributor Defendants' failed efforts to create and effectively implement anti-diversion policies drew the scrutiny of federal and state agencies.

McKesson

709. In May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that McKesson had failed to maintain effective controls against diversion of controlled substances in Florida, Maryland, Colorado, Texas, Utah, and California (the "2008 McKesson Settlement Agreement").

710. McKesson agreed to pay a $13.25 million civil fine for its failure to report suspicious orders from rogue internet pharmacies around the country that resulted in millions of doses of controlled substances being diverted.

711. McKesson also "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA." Specifically, McKesson agreed to "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders and follow the procedures established by its [CSMP]."

712. However, McKesson's system for detecting suspicious orders from pharmacies was so ineffective and dysfunctional that, in a five-year period, it filled more than 1.6 million orders, but reported just 16 orders as suspicious – all from just a single consumer.

713. Pursuant to the 2008 McKesson Settlement Agreement, McKesson implemented a CSMP which was in place from 2008 to 2014, establishing threshold monthly doses that, if surpassed, would purportedly trigger an investigation into whether an order is suspicious. [redacted]

714. Because of continuous compliance failures, after the 2008 McKesson Settlement Agreement and leading up to 2014, McKesson continued to draw the scrutiny of state and federal regulators and law enforcement officials. [redacted]

715. [redacted]

716. In January 2017, McKesson again admitted its failure to adequately monitor, report, and prevent suspicious orders of oxycodone and hydrocodone by entering into a Settlement Agreement and Release with the DEA and the United States Department of Justice (the "2017 McKesson Settlement Agreement").

717. The 2017 McKesson Settlement Agreement required McKesson to pay a record $150 million civil penalty for violations of the CSA for its operations in California, Colorado, Florida, Illinois, Massachusetts, Michigan, Missouri, Kentucky, Nebraska, New Jersey, Ohio, Washington, West Virginia, and Wisconsin.

718. McKesson admitted in that settlement agreement that, between January 2009 and January 2017, it "did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson "failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b)."

719. McKesson further admitted that it had "distributed controlled substances to pharmacies even though those [McKesson] Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a)." McKesson admitted that it had "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations."

720. As part of the 2017 McKesson Settlement Agreement, McKesson admitted that these violations had included its distribution center located in Aurora, Illinois. Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Aurora, Illinois facility would be partially suspended for several years. The overall sanctions included in the 2017 Settlement Agreement were the most severe ever imposed on a DEA-registered distributor.

Cardinal

721. In 2008, the DEA took action against Cardinal for opioid diversion taking place at seven warehouses around the United States (the "2008 Cardinal Settlement Agreement"). These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue internet pharmacy websites.

722. In connection with the 2008 Cardinal Settlement Agreement, the DEA stated that "[d]espite [its] repeated attempts to educate Cardinal Health on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for controlled substances filled by its distribution facilities located throughout the United States." The DEA concluded that "Cardinal's conduct allowed the 'diversion' of millions of dosage units of hydrocodone from legitimate to non-legitimate channels."

723. In 2012, Cardinal reached another settlement with the DEA relating to systemic opioid diversion in its Florida distribution center (the "2012 Cardinal Settlement Agreement"). Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies.

724. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to

conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA, on or before May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.

725. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes, this time for $44 million (the "2016 Cardinal Settlement Agreement"). The settlement covered DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida. The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case. The settlement also covered a Cardinal subsidiary, Kinray, LLC, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate.

AmerisourceBergen

726. AmerisourceBergen has had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

727. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to internet pharmacies. According to the DEA, over the course of one year, AmerisourceBergen had distributed 3.8 million dosage units of hydrocodone to "rogue pharmacies." The DEA suspended AmerisourceBergen's registration after determining that "the continued registration of this company constitutes an imminent danger to public health and safety."

728. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.

Despite prior regulatory actions, the Distributor Defendants continued their misconduct in Illinois

729. The Distributor Defendants shipped hundreds of millions of opioids to Illinois. [redacted]

730. Each of the Distributor Defendants knew or should have known that the amount of opioids that it allowed to flow into Illinois far exceeded what could be consumed for medically necessary purposes in the relevant communities.

731. Yet the Distributor Defendants failed to control their supply lines to prevent diversion. Specifically, they:

a. hired employees with insufficient experience or expertise in compliance matters and failed to provide employees with proper training or supervision;

b. failed to provide adequate oversight, security, and control of supply channels;

c. failed to properly investigate the pharmacists and doctors who were purchasing large quantities of commonly abused opioids in amounts much greater than justified by the size of the local populations;

d. did not investigate demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around Illinois; and

e. provided little to no guidance to pharmacies and retailers about opioid diversion.

732. The Distributor Defendants used compensation structures that prioritized profits over compliance with suspicious order monitoring. In fact, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by how many opioids

they sold to pharmacies and other facilities servicing Illinois, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

733. The Distributor Defendants failed to report suspicious orders originating in Illinois to either the DEA or the state regulatory agencies, and/or filled such orders without taking appropriate steps to investigate, address, or prevent the suspected diversion.

734. The Distributor Defendants filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency that originated in Illinois.

735. The Distributor Defendants failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," as required by 21 C.F.R. § 1301.74(b), and failed to exercise "good faith" in dispensing opioids as required under Illinois law. 720 ILCS 570/102(u); *see also* 225 ILCS 120/55(a)(4).

736. The Distributor Defendants made little to no effort to perform sufficient due diligence inspections for Illinois pharmacies to ensure that the controlled substances Defendants had furnished were not being diverted to illegal uses. Even when some due diligence was performed, the Distributor Defendants often failed to follow up on red flags or terminate distribution relationships after numerous red flags surfaced.

737. Costs to the State are a direct and proximate result of the Distributor Defendants' having unlawfully ignored opioid diversion, thus contributing to an illegitimate market for opioids.

738. If the Distributor Defendants had adhered to effective controls to guard against diversion, Illinois and its citizens would have avoided significant injury and loss.

739. Instead, the Distributor Defendants made substantial profits based on their failure to prevent illegal diversion of opioids into illegitimate channels in Illinois.

Opioids Have Severely Impacted Illinois

740. Like the rest of the country, Illinois is in the midst of an unprecedented opioid epidemic.

741. Opioid use, morbidity, and mortality have increased exponentially in the State of Illinois in the years since Defendants first began aggressively marketing and distributing opioids. The total number of opioid prescriptions filled in Illinois increased by 25%, or nearly 2 million prescriptions, from 2008 to when it peaked in 2014.

742. Even as prescription rates have declined in recent years, the large number of opioid sales in Illinois continue to pose grave concerns. For example, in 2018, 2,102,727 Illinois patients received a total of 4,850,691 prescriptions. In 2018, the average supply per prescription was one hundred and one days of the medication, up from an average supply of ninety-eight days in 2017.

743. Opioid-related overdose deaths in Illinois in 2017 exceeded the national rate. In 2017, there were 2,202 drug over deaths involving opioids, a rate of 17.2 deaths per 100,000 persons which is higher than the national rate of 14.6 deaths per 100,000 persons. The greatest increase in opioid deaths was seen in cases involving synthetic opioids (mainly fentanyl) - a rise from 127 deaths in 2014 to 1,187 deaths in 2017. Deaths involving heroin also increased significantly in the 3 year period – from 844 to 1,251 deaths. There were 623 deaths involving prescriptions opioids in 2017, nearly double the 343 deaths in 2014.[106]

744. Overdose deaths – specifically opioid overdose – have overtaken those causes that have traditionally had the highest rates of accidental death. In 2016, opioid-related overdoses claimed the lives of 1,946 Illinoisans. This is more than one and a half times the number of homicides

[106] National Institute on Drug Abuse Illinois Opioid Summary, available at: https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/illinois-opioid-summary (Last accessed August 30, 2019).

and nearly twice the number of fatal car accidents.[107] The number of deaths then rose to 2,202 in 2017.

745. The 2,202 opioid overdose fatalities in 2017 represented a more than 100% increase since 2013.[108] In 2018, the number of opioid overdose fatalities continued to exceed 2,000.[109]

746. Opioid overdoses are a statewide problem affecting urban, suburban, and rural communities.

747. The scope of human suffering and economic cost of opioids on Illinois reverberates far beyond overdose mortality rate. The State spends significant public resources on medical services, law enforcement, corrections, worker's compensation, diversion programs, prosecution, probation, treatment, and child welfare.

748. Between Q1 2014 and Q3 2016, statewide hospitalization rates for all opioid overdoses increased 42%, opioid analgesic overdoses increased 45% and heroin overdoses increased 39%.[110] These numbers continue to rise at alarming rates, with the number of emergency department visits for suspected opioid overdoses increasing by 66% in Illinois between July 2016 and September 2017.[111]

749. Emergency medical service (EMS) providers are often the first responders on the scene of an opioid overdose. Under the Heroin Crisis Act, all EMS vehicles in Illinois must be equipped with naloxone, a drug that can quickly reverse an opioid overdose. 9,272 EMS naloxone administrations were reported to the Illinois Department of Public Health for 2015, a

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[107] State of Illinois Comprehensive Opioid Data Report, *supra* note 24, at p. 3.
[108] Illinois Department of Public Health Opioid Data Dashboard, available at: https://idph.illinois.gov/OpioidDataDashboard/ (Last accessed August 29, 2019).
[109] *Id.*
[110] State of Illinois Comprehensive Opioid Data Report, *supra* note 24, at p. 12.
[111] Emergency Department Data Show Rapid Increases in Opioid Overdoses, CDC Press Release, Mar. 6, 2018, available at: https://www.cdc.gov/media/releases/2018/p0306-vs-opioids-overdoses.html (Last accessed August 30, 2019).

32.6% increase over 2013. Further, in large part due to the presence of fentanyl and other synthetic opioids in substances being used, the number of EMS runs that required two administrations of naloxone increased by over 50% from 2013-2015, and the number of runs requiring three administrations increased over 75%.[112]

750. In 2017, Chicago Fire Department crews were dispatched to 9,158 opioid-related overdoses, with over 1,250 of those calls coming from just a four-block area on the city's West Side.[113] Local residents battle to keep the drug dealers away, but they are ever-present, even known to regularly host "serves" in a nearby alley, providing free samples to users.[114] The drug trade is so rampant that drug users will line up and wait outside in broad daylight to get into a building where heroin dealers operate.[115]

751. 19,289, or nearly 30%, of publicly-funded drug treatment admissions in Illinois in 2015 were for persons who indicated opioids as their primary substance of abuse.[116]

752. In 2016, 2,241 Illinois prisoners indicated opioids as their primary substance of misuse. In 2017, nine Illinois drug and mental health courts reported one-third of their participants had an opioid use-related diagnosis.[117]

753. Defendants' unfair and deceptive conduct also has a significant detrimental impact on children in Illinois. In 2013-2014, 40,000 teens per year in Illinois reported non-medical use of

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[112] State of Illinois, The Opioid Crisis in Illinois Data and the State's Response, *supra* note 47, at p. 3.
[113] Ali, Tanveer and Sam Charles, "A 4-block radius on the West Side is at the heart of Chicago's opioid epidemic," May 25, 2018, available at: https://chicago.suntimes.com/news/opioids-heroin-fentanyl-west-side-data/ (Last accessed August 30, 2019).
[114] *Id.*
[115] "West Side Drug Dealer Had Customers Lined Up Around Corner: Feds," June 25, 2015, available at: https://www.nbcchicago.com/news/local/West-Side-Drug-Dealer-Had-Customers-Lined-Up-Around-Corner-309764301.html (Last accessed August 30, 2019).
[116] State of Illinois, The Opioid Crisis in Illinois Data and the State's Response, *supra* note 47, at p. 6.
[117] Reichert, *supra* note 26, at p. 3.

prescriptions opioids.[118] Adolescent misuse of prescription opioids is very important, because it is the peak period in life when people first misuse opioids. The adolescent brain is still maturing and particularly susceptible to opioids. Even if opioid use does not lead to addiction or overdose deaths in youth and adolescents, research demonstrates the profound impacts of opioids on the developing brain. The overprescribing of opioids for chronic pain has given young children access to opioids, nearly all of which were prescribed for adults in their household or to the children by dentists.

754. Even infants have not been immune to the impact of opioid abuse and over-prescription. There has been a dramatic increase in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome (NAS), which can occur in an infant exposed in utero to addictive, illegal or prescription drugs.

755. In 2016 alone, nearly 400 babies were born in Illinois suffering from NAS.[119]

756. There are substantial costs associated with these births, and the syndrome is particularly prevalent in infants covered by public insurance and who are uninsured. Babies born with NAS may experience a variety of withdrawal symptoms, medical complications and have prolonged hospital stays. In Illinois, in 2016, the median length of hospital stay after birth was eleven days longer for infants with NAS, compared to those without. The median hospital charges for infants with NAS were more than seven times higher than for infants without NAS, with the total charges for hospital care for infants born with NAS being nearly $18 million higher than what would have been expected if they had been born without NAS.[120]

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[118] State of Illinois Opioid Action Plan, September 2017, at p. 17, available at: http://dph.illinois.gov/sites/default/files/publications/Illinois-Opioid-Action-Plan-Sept-6-2017-FINAL.pdf (Last accessed August 30, 2019).

[119] Neonatal Abstinence Syndrome, Illinois Department of Public Health, available at: http://www.dph.illinois.gov/topics-services/prevention-wellness/prescription-opioids-and-heroin/neonatal-abstinence-syndrome (Last accessed August 30, 2019).

[120] *Id.*

757. Opioid use has had a significant impact on the nation's child welfare system, as parental substance abuse is a major risk factor for child fatalities, child maltreatment, and involvement with the child welfare system. In 2016, the number of new foster care cases involving parents who are using drugs hit the highest point in more than three decades,[121] a trend undoubtedly affecting Illinois' child welfare system.

758. The impacts of opioids on Illinois are inextricably linked with the Manufacturer Defendants' marketing practices designed to convince prescribers, patients, and the public that opioids were a drug that could be used long-term and at high doses with little risk of addiction or serious complications and with the Distributor Defendants' failure to adequately identify, monitor, report or otherwise take appropriate action in response to suspicious opioid orders.

759. Defendants knew opioids were dangerous and were causing harm, yet they continued to massively push these products into more and more consumers' hands.

760. As a result, opioid use has grown to epidemic proportions and the death rates, including in Illinois, continue to rise while Defendants continue to market, sell and/or distribute drugs that they know are deadly.

761. The Attorney General asks this Court to stop Defendants' unfair and deceptive conduct and order legal and equitable remedies to begin addressing the opioid epidemic in our state.

APPLICABLE STATUTES

762. Section 2 of the Consumer Fraud Act provides:

> Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely

[121] Associated Press, "Opioid crisis straining foster systems as kids pried from homes," Dec. 12, 2017, available at: https://www.nbcnews.com/storyline/americas-heroin-epidemic/opioid-crisis-strains-foster-system-kids-pried-homes-n828831 (Last accessed August 30, 2019).

upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act. 815 ILCS 505/2.

FIRST CAUSE OF ACTION

VIOLATIONS OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1-1, *et seq.* (JANSSEN)

763. The State incorporates Paragraphs 1 through 761 herein as if set forth in their entirety.

764. While engaged in trade or commerce, Janssen committed the following unfair and/or deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2:

a. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the risk of opioid addiction;

b. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the extent to which addiction risk can be managed and addiction prevented;

c. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the mechanisms of action for its opioids;

d. Misrepresenting, with the intent that prescribers and patients rely on its misrepresentations, the true risk of addiction of Janssen's drugs by deceptively using the terms addiction, dependence, tolerance, physical dependence, or "pseudoaddiction";

e. Misrepresenting, with the intent that prescribers and patients rely on those misrepresentations, the symptoms of withdrawal, the challenges entailed in managing those symptoms, and the likelihood or ease with which patients could stop using opioids;

f. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the ability of abuse-deterrent formulations of Janssen's drugs to lower opioid abuse and addiction risk;

g. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about opioids generally and Janssen's products' ability to improve function and quality of life long-term;

h. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, that increased doses of opioids do not pose significant health risks;

i. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, regarding the risks and benefits of its opioid products compared to those of other opioid products and alternative forms of pain treatment;

j. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the risks of opioid use by the elderly;

k. Unfairly using a marketing and sales scheme intended to overcome prescriber and patient concerns regarding opioid addiction;

l. Unfairly using a marketing and sales scheme intended to keep patients using its dangerous drugs for as long as possible;

m. Unfairly using a marketing and sales scheme intended to increase the doses of its dangerous drugs taken by patients;

n. Unfairly attempting to influence health care providers' prescription decisions for particular patients in sales calls for which the patient was not present;

o. Unfairly targeting senior citizens and veterans for the sale of its dangerous products; and

p. Unfairly targeting and encouraging health care providers with high rates of opioid prescription through in-person detailing, dissemination of educational materials and programs, and third-party materials containing misleading statements about the efficacy and risks of opioids. This targeted marketing sought to cause high volume prescribers to continue prescribing at those rates and encouraging additional prescriptions, even in some cases where Janssen recognized or should have recognized that the health care provider was not meeting the standard of care, and/or that opioids were being diverted or abused, thereby harming the public health.

SECOND CAUSE OF ACTION

VIOLATIONS OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1-1, *et seq.* (ENDO)

765. The State incorporates Paragraphs 1 through 761 herein as if set forth in their entirety.

766. While engaged in trade or commerce, Endo committed the following unfair and/or deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2:

a. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the abuse-deterrent properties of the reformulation of Opana ER and its ability to lower opioid abuse and addiction risk;

b. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the risk of opioid addiction;

c. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the extent to which addiction risk can be managed and addiction prevented;

d. Misrepresenting, with the intent that prescribers and patients rely on its misrepresentations, the true risk of addiction of Endo's drugs by deceptively using the terms addiction, dependence, tolerance, physical dependence, and "pseudoaddiction";

e. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about opioids generally and Endo's products' ability to improve function and quality of life long-term;

f. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, that increased doses of opioids do not pose significant health risks;

g. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, regarding the risks and benefits of its opioid products compared to those of other opioid products;

h. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the risks of opioid use by the elderly;

i. Unfairly using a marketing and sales scheme intended to overcome prescriber and patient concerns regarding opioid addiction;

j. Unfairly targeting senior citizens for the sale of its dangerous products;

k. Unfairly using a marketing and sales scheme intended to keep patients using its dangerous drugs for as long as possible;

l. Unfairly using a marketing and sales scheme intended to increase the doses of its dangerous drugs taken by patients; and

m. Unfairly targeting and encouraging health care providers with high rates of opioid prescription through in-person detailing, dissemination of educational materials and programs, and third-party materials containing misleading statements about the efficacy and risks of opioids. This targeted marketing sought to cause high volume prescribers to continue prescribing at those rates and encouraging additional prescriptions, even in some cases where Endo recognized or should have recognized that the health care provider was not meeting the standard of care, and/or that opioids were being diverted or abused, thereby harming the public health.

THIRD CAUSE OF ACTION

VIOLATIONS OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1-1, *et seq.* (TEVA)

767. The State incorporates Paragraphs 1 through 761 herein as if set forth in their entirety.

768. While engaged in trade or commerce, Teva committed the following unfair and/or deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2:

a. Engaging in the unfair and/or deceptive act of targeting Actiq and Fentora promotion at prescribers who do not routinely treat cancer patients;

b. Engaging in the unfair and/or deceptive act of marketing Actiq and Fentora for breakthrough pain not associated with cancer, when in fact, these drugs are not approved for such use;

c. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the risk of opioid addiction;

d. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the extent to which addiction risk can be managed and addiction prevented;

e. Misrepresenting, with the intent that prescribers and patients rely on its misrepresentations, the true risk of addiction of Teva's drugs by deceptively using the terms addiction, dependence, tolerance, physical dependence, and "pseudoaddiction";

f. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about opioids generally and Teva's products' ability to improve function and quality of life long-term;

g. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, that increased doses of opioids do not pose significant health risks;

h. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, regarding the risks and benefits of its opioid products compared to those of alternative forms of pain treatment;

i. Unfairly using a marketing and sales scheme intended to overcome prescriber and patient concerns regarding opioid addiction;

j. Unfairly targeting senior citizens for the sale of its dangerous products;

k. Unfairly using a marketing and sales scheme intended to keep patients using its dangerous drugs for as long as possible;

l. Unfairly using a marketing and sales scheme intended to increase the doses of its dangerous drugs taken by patients;

m. Engaging in the unfair and/or deceptive act of paying prescribers to prescribe Fentora under the guise of its speaker program;

n. Unfairly attempting to influence health care providers' prescription decisions for particular patients in sales calls for which the patient was not present; and

o. Unfairly targeting and encouraging health care providers with high rates of opioid prescription through in-person detailing, dissemination of educational materials and programs, and third-party materials containing misleading statements about the efficacy and risks of opioids. This targeted marketing sought to cause high volume prescribers to continue prescribing at those rates and encouraging additional prescriptions, even in some cases where Teva recognized or should have recognized that the health care provider was not meeting the standard of care, and/or that opioids were being diverted or abused, thereby harming the public health.

FOURTH CAUSE OF ACTION

VIOLATIONS OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1-1, *et seq.* (ALLERGAN)

769. The State incorporates Paragraphs 1 through 761 herein as if set forth in their entirety.

770. While engaged in trade or commerce, Allergan committed the following unfair and/or deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2:

a. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the risk of opioid addiction;

b. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the extent to which addiction risk can be managed and addiction prevented;

c. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about the ability of the formulations of its drugs to lower opioid abuse and addiction risk;

d. Misrepresenting, with the intent that prescribers and patients rely on its misrepresentations, the true risk of addiction of Allergan's drugs by deceptively using the terms addiction, dependence, tolerance, physical dependence, and "pseudoaddiction";

e. Misrepresenting, with the intent that prescribers and patients rely on those misrepresentations, the symptoms of withdrawal, the challenges entailed in managing those symptoms, and the likelihood or ease with which patients could stop using opioids;

f. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, about opioids generally and Allergan's products' ability to improve function and quality of life long-term;

g. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, that increased doses of opioids do not pose significant health risks;

h. Making misrepresentations and unsubstantiated claims, with the intent that prescribers and patients rely on those misrepresentations, regarding the risks and benefits of its opioid products compared to those of other opioid products and alternative forms of pain treatment;

i. Unfairly using a marketing and sales scheme intended to overcome prescriber and patient concerns regarding opioid addiction;

j. Unfairly using a marketing and sales scheme intended to keep patients using its dangerous drugs for as long as possible;

k. Unfairly using a marketing and sales scheme intended to increase the doses of its dangerous drugs taken by patients; and

l. Unfairly targeting and encouraging health care providers with high rates of opioid prescription through in-person detailing and dissemination of educational materials and programs. This targeted marketing sought to cause high volume prescribers to continue prescribing at those rates and encouraging additional prescriptions, even in some cases where Allergan recognized or should have recognized that the health care provider was not meeting the standard of care, and/or that opioids were being diverted or abused, thereby harming the public health.

FIFTH CAUSE OF ACTION

VIOLATIONS OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1-1, *et seq.* (MCKESSON)

771. The State incorporates Paragraphs 1 through 761 herein as if set forth in their entirety.

772. While engaged in trade or commerce, McKesson committed the following unfair and/or deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2:

a. Unfairly failing to adequately monitor and/or identify suspicious orders for opioids pursuant to state and federal laws;

b. Unfairly failing to conduct adequate due diligence to ensure that it was only filling legitimate orders for legitimate customers;

c. Unfairly filling tens of thousands of orders without adequate due diligence or reporting suspicious orders to law enforcement, in violation of federal and state law;

d. Unfairly filling tens of thousands of orders which it knew or should have known were likely to be diverted into illegitimate channels;

e. Unfairly failing to report, concealing from relevant law enforcement and medical regulators, or otherwise take appropriate action in response to suspicious,

excessive, and illegal opioid ordering practices, while profiting from inflated orders of opioids; and

f. Engaging in a deceptive and unfair scheme to increase sales of its opioid drugs by ignoring its duty and/or using inadequate measures to identify and prevent the shipment of suspicious and illegal orders of opioid drugs.

SIXTH CAUSE OF ACTION

VIOLATIONS OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1-1, et seq. (CARDINAL)

773. The State incorporates Paragraphs 1 through 761 herein as if set forth in their entirety.

774. While engaged in trade or commerce, Cardinal committed the following unfair and/or deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2:

a. Unfairly failing to adequately monitor and/or identify suspicious orders for opioids pursuant to state and federal laws;

b. Unfairly failing to conduct adequate due diligence to ensure that it was only filling legitimate orders for legitimate customers;

c. Unfairly filling tens of thousands of orders without adequate due diligence or reporting suspicious orders to law enforcement, in violation of federal and state law;

d. Unfairly filling tens of thousands of orders which it knew or should have known were likely to be diverted into illegitimate channels;

e. Unfairly failing to report, concealing from relevant law enforcement and medical regulators, or otherwise take appropriate action in response to suspicious, excessive, and illegal opioid ordering practices, while profiting from inflated orders of opioids; and

f. Engaging in a deceptive and unfair scheme to increase sales of its opioid drugs by ignoring its duty and/or using inadequate measures to identify and prevent the shipment of suspicious and illegal orders of opioid drugs.

SEVENTH CAUSE OF ACTION

VIOLATIONS OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1-1, *et seq.* (AMERISOURCEBERGEN)

775. The State incorporates Paragraphs 1 through 761 herein as if set forth in their entirety.

776. While engaged in trade or commerce, AmerisourceBergen committed the following unfair and/or deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2:

a. Unfairly failing to adequately monitor and/or identify suspicious orders for opioids pursuant to state and federal laws;

b. Unfairly failing to conduct adequate due diligence to ensure that it was only filling legitimate orders for legitimate customers;

c. Unfairly filling tens of thousands of orders without adequate due diligence or reporting suspicious orders to law enforcement, in violation of federal and state law;

d. Unfairly filling tens of thousands of orders which it knew or should have known were likely to be diverted into illegitimate channels;

e. Unfairly failing to report, concealing from relevant law enforcement and medical regulators, or otherwise take appropriate action in response to suspicious, excessive, and illegal opioid ordering practices, while profiting from inflated orders of opioids; and

f. Engaging in a deceptive and unfair scheme to increase sales of its opioid drugs by ignoring its duty and/or using inadequate measures to identify and prevent the shipment of suspicious and illegal orders of opioid drugs.

EIGHTH CAUSE OF ACTION

PUBLIC NUISANCE (JANSSEN)

777. The State incorporates Paragraphs 1 through 761 above as if set forth in their entirety.

778. A public nuisance is something that negatively affects the public's health, safety, or morals, or causes substantial annoyance, inconvenience, or injury to the public.

779. Illinois residents have a public right to health, safety, peace, and comfort. Those rights are a matter of great interest and of legitimate concern to the State, which has a duty to protect the health, safety, and well-being of its residents. The Attorney General has the power and authority to bring suit to abate a public nuisance.

780. Janssen is required to abide by the Illinois Controlled Substance Act, in which the Illinois General Assembly specifically recognized, "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100.

781. Janssen also has a duty under the Consumer Fraud Act to refrain from disseminating deceptive or misleading promotional material and a duty under the Consumer Fraud Act to disclose material facts. Janssen violated these duties.

782. As described in detail above, Janssen's deceptive and misleading marketing practices substantially and unreasonably interfered with the public rights to health, safety, comfort, and peace. For example, as a result of Janssen's conduct:

a. Opioid use, abuse, and overdose deaths have significantly increased throughout Illinois;

b. Buildings and public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to overprescribing, and the foreseeable failure to safely dispose of opioids;

c. The greater demand for emergency services, law enforcement, addiction treatment, and social services has placed an unreasonable burden on State and local resources;

d. Expanding the market for prescription opioids to primary care patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury;

e. Additional illicit markets in other opiates have been created, particularly for heroin. Many users who were initially dependent on prescription opioids and then

were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process;

f. Health care costs have increased for individuals, families, and the State; and

g. Health care providers who were profitable to Janssen but harmful to the public continued prescribing increasing numbers of opioids throughout the State in light of Janssen's failure to report suspicions of illicit prescribing to the State or law enforcement.

783. Janssen controlled and controls the "instrumentality" of the nuisance – its marketing of opioid medications, including the deceptive and misleading representations regarding particular opioid medications, and the deceptive and misleading marketing schemes Janssen used to disseminate messages about opioids in general, and failing to appropriately monitor and report the potential abuse and diversion of opioids.

784. Janssen's deceptive and unfair conduct was a direct and proximate cause of opioids becoming widely available, used, and all too often abused. Janssen's actions proximately caused prescribers' and patients' inability to assess and weigh the risks and benefits of opioids, resulting in pervasive overprescribing and abuse of these drugs. No third party broke the causal chain between Janssen's wrongful conduct and the resulting harm.

785. But for Janssen's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. Janssen's actions have harmed and will continue to harm many residents throughout Illinois, including opioid users, their families, and their communities at large.

786. The intent of Janssen's promotion of opioids was to sell more of them. Janssen intended for health care providers to prescribe more opioids, for patients to fill those prescriptions, and then for that prescription pattern to continue, often at higher and higher doses.

787. The public nuisance and associated financial and economic losses resulting from Janssen's deceptive and unfair conduct were foreseeable to Janssen, which knew or should have known that its conduct would create a public health crisis. As alleged herein, Janssen engaged in widespread deceptive and unfair promotion of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death. In addition to being unlawful, Janssen's conduct was also unreasonable and negligent in light of the lack of scientific support for Janssen's claims, and reckless and/or intentional in light of the known risks associated with opioids.

788. A reasonable pharmaceutical manufacturer in Janssen's position would have foreseen not only a vastly expanded market for opioids, but also the related likely and foreseeable result of Janssen's conduct – the widespread problems of opioid addiction and abuse. In fact, Janssenwas on notice and aware of signs that health care providers were prescribing unreasonably higher numbers of opioids and that the broader use of opioids was causing just the kinds of injuries described in this Complaint, but it continued to make deceptive and misleading statements to promote opioids.

789. Janssen's deceptive business practices ultimately generated a new and very profitable circular market – providing both the supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

790. The injuries resulting from Janssen's deceptive and unfair conduct described above are severe, including opioid addiction, overdose, and death, as well as increased health care costs and loss of productivity. The State has suffered special injuries different from the general public, including the substantial costs associated with the investigation, monitoring, treatment, policing, and other remediation of the opioid epidemic.

791. Janssen acted without express authority of a statute or law when it engaged in the deceptive and unfair practices described herein.

792. Janssen's conduct was not insubstantial or fleeting; to the contrary, Janssen substantially and unreasonably interfered with public rights, and proximately caused and continues to cause significant injury to the public. Janssen's wrongful conduct is ongoing and persistent, and continues to cause tremendous injury to the public and the State to incur significant costs.

793. The public nuisance – i.e., the opioid epidemic – created, maintained, and perpetuated by Janssen can be abated, and further recurrence of such harm and inconvenience can be abated, by (a) ceasing any further marketing of Janssen's opioid products; (b) ceasing the further dissemination of any misleading information about opioids in general; (c) educating prescribers (especially primary care physicians, nurse practitioners, physician assistants, and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction; (d) educating young people in particular about the risks of addiction; (e) educating women in particular about the risks of opioid use during pregnancy, including neonatal abstinence syndrome; (f) creating a publicly-accessible repository for independent, peer-reviewed studies on the risks and benefits of opioids; (g) providing and expanding access to addiction treatment to patients who are already addicted to opioids; and (h) making overdose reversal drugs widely available so that overdoses are less frequently fatal, among other measures.

794. The State seeks an order that provides for abatement of the public nuisance Janssen has created, enjoins Janssen from further deceptive and unfair conduct, and awards the State the costs associated with abatement of the nuisance and harm to the State in an amount to be determined at trial.

NINTH CAUSE OF ACTION

PUBLIC NUISANCE (ENDO)

795. The State incorporates Paragraphs 1 through 761 above as if set forth in their entirety.

796. A public nuisance is something that negatively affects the public's health, safety, or morals, or causes substantial annoyance, inconvenience, or injury to the public.

797. Illinois residents have a public right to health, safety, peace, and comfort. Those rights are a matter of great interest and of legitimate concern to the State, which has a duty to protect the health, safety, and well-being of its residents. The Attorney General has the power and authority to bring suit to abate a public nuisance.

798. Endo is required to abide by the Illinois Controlled Substance Act, in which the Illinois General Assembly specifically recognized, "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100.

799. Endo also has a duty under the Consumer Fraud Act to refrain from disseminating deceptive or misleading promotional material and a duty under the Consumer Fraud Act to disclose material facts. Endo violated these duties.

800. As described in detail above, Endo's deceptive and misleading marketing practices substantially and unreasonably interfered with the public rights to health, safety, comfort, and peace. For example, as a result of Endo's conduct:

a. Opioid use, abuse, and overdose deaths have significantly increased throughout Illinois;

b. Buildings and public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to overprescribing, and the foreseeable failure to safely dispose of opioids;

c. The greater demand for emergency services, law enforcement, addiction treatment, and social services has placed an unreasonable burden on State and local resources;

d. Expanding the market for prescription opioids to primary care patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury;

e. Additional illicit markets in other opiates have been created, particularly for heroin. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process;

f. Health care costs have increased for individuals, families, and the State; and

g. Health care providers who were profitable to Endo but harmful to the public continued prescribing increasing numbers of opioids throughout the State in light of Endo's failure to report suspicions of illicit prescribing to the State or law enforcement.

801. Endo controlled and controls the "instrumentality" of the nuisance – its marketing of opioid medications, including the deceptive and misleading representations regarding particular opioid medications, and the deceptive and misleading marketing schemes Endo used to disseminate messages about opioids in general, and failing to appropriately monitor and report the potential abuse and diversion of opioids.

802. Endo's deceptive and unfair conduct was a direct and proximate cause of opioids becoming widely available, used, and all too often abused. Endo's actions proximately caused prescribers' and patients' inability to assess and weigh the risks and benefits of opioids, resulting in pervasive overprescribing and abuse of these drugs. No third party broke the causal chain between Endo's wrongful conduct and the resulting harm.

803. But for Endo's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would

have been averted. Endo's actions have harmed and will continue to harm many residents throughout Illinois, including opioid users, their families, and their communities at large.

804. The intent of Endo's promotion of opioids was to sell more of them. Endo intended for health care providers to prescribe more opioids, for patients to fill those prescriptions, and then for that prescription pattern to continue, often at higher and higher doses.

805. The public nuisance and associated financial and economic losses resulting from Endo's deceptive and unfair conduct were foreseeable to Endo, which knew or should have known that its conduct would create a public health crisis. As alleged herein, Endo engaged in widespread deceptive and unfair promotion of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death. In addition to being unlawful, Endo's conduct was also unreasonable and negligent in light of the lack of scientific support for Endo's claims, and reckless and/or intentional in light of the known risks associated with opioids.

806. A reasonable pharmaceutical manufacturer in Endo's position would have foreseen not only a vastly expanded market for opioids, but also the related likely and foreseeable result of Endo's conduct – the widespread problems of opioid addiction and abuse. In fact, Endo was on notice and aware of signs that health care providers were prescribing unreasonably higher numbers of opioids and that the broader use of opioids was causing just the kinds of injuries described in this Complaint, but it continued to make deceptive and misleading statements to promote opioids.

807. Endo's deceptive business practices ultimately generated a new and very profitable circular market – providing both the supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

808. The injuries resulting from Endo's deceptive and unfair conduct described above are severe, including opioid addiction, overdose, and death, as well as increased health care costs and loss of productivity. The State has suffered special injuries different from the general public, including the substantial costs associated with the investigation, monitoring, treatment, policing, and other remediation of the opioid epidemic.

809. Endo acted without express authority of a statute or law when it engaged in the deceptive and unfair practices described herein.

810. Endo's conduct was not insubstantial or fleeting; to the contrary, Endo substantially and unreasonably interfered with public rights, and proximately caused and continues to cause significant injury to the public. Endo's wrongful conduct is ongoing and persistent, and continues to cause tremendous injury to the public and the State to incur significant costs.

811. The public nuisance – i.e., the opioid epidemic – created, maintained, and perpetuated by Endo can be abated, and further recurrence of such harm and inconvenience can be abated, by (a) ceasing any further marketing of Endo's opioid products; (b) ceasing the further dissemination of any misleading information about opioids in general; (c) educating prescribers (especially primary care physicians, nurse practitioners, physician assistants, and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction; (d) educating young people in particular about the risks of addiction; (e) educating women in particular about the risks of opioid use during pregnancy, including neonatal abstinence syndrome; (f) creating a publicly-accessible repository for independent, peer-reviewed studies on the risks and benefits of opioids; (g) providing and expanding access to addiction treatment to patients who are already addicted to opioids; and (h) making overdose reversal drugs widely available so that overdoses are less frequently fatal, among other measures.

The State seeks an order that provides for abatement of the public nuisance Endo has created, enjoins Endo from further deceptive and unfair conduct, and awards the State the costs associated with abatement of the nuisance and harm to the State in an amount to be determined at trial.

TENTH CAUSE OF ACTION

PUBLIC NUISANCE (TEVA)

812. The State incorporates Paragraphs 1 through 761 above as if set forth in their entirety.

813. A public nuisance is something that negatively affects the public's health, safety, or morals, or causes substantial annoyance, inconvenience, or injury to the public.

814. Illinois residents have a public right to health, safety, peace, and comfort. Those rights are a matter of great interest and of legitimate concern to the State, which has a duty to protect the health, safety, and well-being of its residents. The Attorney General has the power and authority to bring suit to abate a public nuisance.

815. Teva is required to abide by the Illinois Controlled Substance Act, in which the Illinois General Assembly specifically recognized, "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100.

816. Teva also has a duty under the Consumer Fraud Act to refrain from disseminating deceptive or misleading promotional material and a duty under the Consumer Fraud Act to disclose material facts. Teva violated these duties.

817. As described in detail above, Teva's deceptive and misleading marketing practices substantially and unreasonably interfered with the public rights to health, safety, comfort, and peace. For example, as a result of Teva's conduct:

a. Opioid use, abuse, and overdose deaths have significantly increased throughout Illinois;

b. Buildings and public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to overprescribing, and the foreseeable failure to safely dispose of opioids;

c. The greater demand for emergency services, law enforcement, addiction treatment, and social services has placed an unreasonable burden on State and local resources;

d. Expanding the market for prescription opioids to primary care patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury;

e. Additional illicit markets in other opiates have been created, particularly for heroin. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process;

f. Health care costs have increased for individuals, families, and the State; and

g. Health care providers who were profitable to Teva but harmful to the public continued prescribing increasing numbers of opioids throughout the State in light of Teva's failure to report suspicions of illicit prescribing to the State or law enforcement.

818. Teva controlled and controls the "instrumentality" of the nuisance – its marketing of opioid medications, including the deceptive and misleading representations regarding particular opioid medications, and the deceptive and misleading marketing schemes Teva used to disseminate messages about opioids in general, and failing to appropriately monitor and report the potential abuse and diversion of opioids.

819. Teva's deceptive and unfair conduct was a direct and proximate cause of opioids becoming widely available, used, and all too often abused. Teva's actions proximately caused prescribers' and patients' inability to assess and weigh the risks and benefits of opioids, resulting

in pervasive overprescribing and abuse of these drugs. No third party broke the causal chain between Teva's wrongful conduct and the resulting harm.

820. But for Teva's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. Teva's actions have harmed and will continue to harm many residents throughout Illinois, including opioid users, their families, and their communities at large.

821. The intent of Teva's promotion of opioids was to sell more of them. Teva intended for health care providers to prescribe more opioids, for patients to fill those prescriptions, and then for that prescription pattern to continue, often at higher and higher doses.

822. The public nuisance and associated financial and economic losses resulting from Teva's deceptive and unfair conduct were foreseeable to Teva, which knew or should have known that its conduct would create a public health crisis. As alleged herein, Teva engaged in widespread deceptive and unfair promotion of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death. In addition to being unlawful, Teva's conduct was also unreasonable and negligent in light of the lack of scientific support for Teva's claims, and reckless and/or intentional in light of the known risks associated with opioids.

823. A reasonable pharmaceutical manufacturer in Teva's position would have foreseen not only a vastly expanded market for opioids, but also the related likely and foreseeable result of Teva's conduct – the widespread problems of opioid addiction and abuse. In fact, Teva was on notice and aware of signs that health care providers were prescribing unreasonably higher numbers of opioids and that the broader use of opioids was causing just the kinds of injuries described in this Complaint, but it continued to make deceptive and misleading statements to promote opioids.

824. Teva's deceptive business practices ultimately generated a new and very profitable circular market – providing both the supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

825. The injuries resulting from Teva's deceptive and unfair conduct described above are severe, including opioid addiction, overdose, and death, as well as increased health care costs and loss of productivity. The State has suffered special injuries different from the general public, including the substantial costs associated with the investigation, monitoring, treatment, policing, and other remediation of the opioid epidemic.

826. Teva acted without express authority of a statute or law when it engaged in the deceptive and unfair practices described herein.

827. Teva's conduct was not insubstantial or fleeting; to the contrary, Teva substantially and unreasonably interfered with public rights, and proximately caused and continues to cause significant injury to the public. Teva's wrongful conduct is ongoing and persistent, and continues to cause tremendous injury to the public and the State to incur significant costs.

828. The public nuisance – i.e., the opioid epidemic – created, maintained, and perpetuated by Teva can be abated, and further recurrence of such harm and inconvenience can be abated, by (a) ceasing any further marketing of Teva's opioid products; (b) ceasing the further dissemination of any misleading information about opioids in general; (c) educating prescribers (especially primary care physicians, nurse practitioners, physician assistants, and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction; (d) educating young people in particular about the risks of addiction; (e) educating women in particular about the risks of opioid use during pregnancy, including neonatal abstinence syndrome; (f) creating a publicly-accessible repository for independent, peer-

reviewed studies on the risks and benefits of opioids; (g) providing and expanding access to addiction treatment to patients who are already addicted to opioids; and (h) making overdose reversal drugs widely available so that overdoses are less frequently fatal, among other measures.

829. The State seeks an order that provides for abatement of the public nuisance Teva has created, enjoins Teva from further deceptive and unfair conduct, and awards the State the costs associated with abatement of the nuisance and harm to the State in an amount to be determined at trial.

ELEVENTH CAUSE OF ACTION

PUBLIC NUISANCE (ALLERGAN)

830. The State incorporates Paragraphs 1 through 761 above as if set forth in their entirety.

831. A public nuisance is something that negatively affects the public's health, safety, or morals, or causes substantial annoyance, inconvenience, or injury to the public.

832. Illinois residents have a public right to health, safety, peace, and comfort. Those rights are a matter of great interest and of legitimate concern to the State, which has a duty to protect the health, safety, and well-being of its residents. The Attorney General has the power and authority to bring suit to abate a public nuisance.

833. Allergan is required to abide by the Illinois Controlled Substance Act, in which the Illinois General Assembly specifically recognized, "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100.

834. Allergan also has a duty under the Consumer Fraud Act to refrain from disseminating deceptive or misleading promotional material and a duty under the Consumer Fraud Act to disclose material facts. Allergan violated these duties.

835. As described in detail above, Allergan's deceptive and misleading marketing practices substantially and unreasonably interfered with the public rights to health, safety, comfort, and peace. For example, as a result of Allergan's conduct:

a. Opioid use, abuse, and overdose deaths have significantly increased throughout Illinois;

b. Buildings and public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to overprescribing, and the foreseeable failure to safely dispose of opioids;

c. The greater demand for emergency services, law enforcement, addiction treatment, and social services has placed an unreasonable burden on State and local resources;

d. Expanding the market for prescription opioids to primary care patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury;

e. Additional illicit markets in other opiates have been created, particularly for heroin. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process;

f. Health care costs have increased for individuals, families, and the State; and

g. Health care providers who were profitable to Allergan but harmful to the public continued prescribing increasing numbers of opioids throughout the State in light of Allergan's failure to report suspicions of illicit prescribing to the State or law enforcement.

836. Allergan controlled and controls the "instrumentality" of the nuisance – its marketing of opioid medications, including the deceptive and misleading representations regarding particular opioid medications, and the deceptive and misleading marketing schemes Allergan used to disseminate messages about opioids in general, and failing to appropriately monitor and report the potential abuse and diversion of opioids.

837. Allergan's deceptive and unfair conduct was a direct and proximate cause of opioids becoming widely available, used, and all too often abused. Allergan's actions proximately caused prescribers' and patients' inability to assess and weigh the risks and benefits of opioids, resulting in pervasive overprescribing and abuse of these drugs. No third party broke the causal chain between Allergan's wrongful conduct and the resulting harm.

838. But for Allergan's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. Allergan's actions have harmed and will continue to harm many residents throughout Illinois, including opioid users, their families, and their communities at large.

839. The intent of Allergan's promotion of opioids was to sell more of them. Allergan intended for health care providers to prescribe more opioids, for patients to fill those prescriptions, and then for that prescription pattern to continue, often at higher and higher doses.

840. The public nuisance and associated financial and economic losses resulting from Allergan's deceptive and unfair conduct were foreseeable to Allergan, which knew or should have known that its conduct would create a public health crisis. As alleged herein, Allergan engaged in widespread deceptive and unfair promotion of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death. In addition to being unlawful, Allergan's conduct was also unreasonable and negligent in light of the lack of scientific support for Allergan's claims, and reckless and/or intentional in light of the known risks associated with opioids.

841. A reasonable pharmaceutical manufacturer in Allergan's position would have foreseen not only a vastly expanded market for opioids, but also the related likely and foreseeable result ofAllergan's conduct – the widespread problems of opioid addiction and abuse. In fact, Allergan

was on notice and aware of signs that health care providers were prescribing unreasonably higher numbers of opioids and that the broader use of opioids was causing just the kinds of injuries described in this Complaint, but it continued to make deceptive and misleading statements to promote opioids.

842. Allergan's deceptive business practices ultimately generated a new and very profitable circular market – providing both the supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

843. The injuries resulting from Allergan's deceptive and unfair conduct described above are severe, including opioid addiction, overdose, and death, as well as increased health care costs and loss of productivity. The State has suffered special injuries different from the general public, including the substantial costs associated with the investigation, monitoring, treatment, policing, and other remediation of the opioid epidemic.

844. Allergan acted without express authority of a statute or law when it engaged in the deceptive and unfair practices described herein.

845. Allergan's conduct was not insubstantial or fleeting; to the contrary, Allergan substantially and unreasonably interfered with public rights, and proximately caused and continues to cause significant injury to the public. Allergan's wrongful conduct is ongoing and persistent, and continues to cause tremendous injury to the public and the State to incur significant costs.

846. The public nuisance – i.e., the opioid epidemic – created, maintained, and perpetuated by Allergan can be abated, and further recurrence of such harm and inconvenience can be abated, by (a) ceasing any further marketing of Allergan's opioid products; (b) ceasing the further dissemination of any misleading information about opioids in general; (c) educating prescribers

(especially primary care physicians, nurse practitioners, physician assistants, and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction; (d) educating young people in particular about the risks of addiction; (e) educating women in particular about the risks of opioid use during pregnancy, including neonatal abstinence syndrome; (f) creating a publicly-accessible repository for independent, peer-reviewed studies on the risks and benefits of opioids; (g) providing and expanding access to addiction treatment to patients who are already addicted to opioids; and (h) making overdose reversal drugs widely available so that overdoses are less frequently fatal, among other measures.

847. The State seeks an order that provides for abatement of the public nuisance Allergan has created, enjoins Allergan from further deceptive and unfair conduct, and awards the State the costs associated with abatement of the nuisance and harm to the State in an amount to be determined at trial.

TWELFTH CAUSE OF ACTION

PUBLIC NUISANCE (MCKESSON)

848. The State incorporates Paragraphs 1 through 761 above as if set forth in their entirety.

849. A public nuisance is something that negatively affects the public's health, safety, or morals, or causes substantial annoyance, inconvenience, or injury to the public.

850. As acknowledged by the DEA, "the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people" and "[f]ailure to maintain effective controls against diversion is inconsistent with the public interest[.]"

851. Illinois residents have a public right to health, safety, peace, and comfort. Those rights are a matter of great interest and of legitimate concern to the State, which has a duty to protect the health, safety, and well-being of its residents. The Attorney General has the power and authority to bring suit to abate a public nuisance.

852. McKesson has a duty under the CSA to maintain and implement effective anti-diversion controls, including identifying, reporting, and halting suspicious orders. See 21 U.S.C. §§ 823(b)(1), 1307.74(b). McKesson is also required to abide by the Illinois Controlled Substance Act, in which the Illinois General Assembly specifically recognized, "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100.

853. McKesson also has a duty under the Consumer Fraud Act to refrain from deceptive or unfair practices in the course of trade or commerce. McKesson unlawfully violated this duty.

854. As described in detail above, McKesson's unlawful practices substantially and unreasonably interfered with the public rights to health, safety, comfort, and peace. For example, as a result of McKesson's conduct:

a. Opioid use, abuse, and overdose deaths have increased throughout Illinois;

b. Buildings and public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to overprescribing, and the foreseeable failure to safely dispose of opioids;

c. The greater demand for emergency services, law enforcement, addiction treatment, and social services has placed an unreasonable burden on State and local resources;

d. Expanding the market for prescription opioids to primary care patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury;

e. Additional illicit markets in other opiates have been created, particularly for heroin. Many users who were initially dependent on prescription opioids and then

were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process;

f. Health care costs have increased for individuals, families, and the State; and

g. Health care providers and pharmacies who were profitable to McKesson but harmful to the public continued prescribing and dispensing increasing numbers of opioids throughout the State in light of McKesson's failure to establish and implement effective abuse and diversion monitoring policies.

855. McKesson controlled and controls the "instrumentality" of the nuisance – its distribution of addictive opioid medications – failing to appropriately monitor, prevent, and report the potential abuse and diversion of opioids.

856. McKesson occupies a pivotal and unique position within the distribution chain and possesses the information, knowledge, skill, and sophistication required of it by federal and state laws to maintain effective controls on the distribution of prescription opioids and to identify, report, and refuse to fill suspicious orders of opioid pharmaceuticals.

857. McKesson, individually and in concert with others, unlawfully provided an oversupply of prescription opioids within the State, thus substantially contributing to the over-prescription and overuse of prescription opioids, including by supplying pill mills and other providers or prescribers who were engaged in an illegal market for the sale of opioids for non-medical purposes.

858. McKesson willfully turned a blind eye and concealed and/or failed to use the knowledge that it had received and fulfilled suspicious orders for overly large quantities of prescription opioids for non-medical purposes.

859. In light of the information, knowledge, skill, and sophistication it possessed, McKesson knew or should have known that it was oversupplying the State with prescription opioids, including by supplying pill mills and other providers or prescribers who were engaged in an illegal market for the sale of opioids for non-medical purposes. The knowing and/or negligent

oversupply by McKesson, individually and in concert with others, has fueled addiction, misuse, and diversion of the drugs for improper purposes.

860. In light of the information, knowledge, skill, and sophistication it possessed, McKesson knew or should have known that orders it received and filled for overly large quantities of prescription opioids were suspicious and that these orders should have been identified and reported, and not fulfilled. McKesson willfully turned a blind eye and concealed and/or failed to use the knowledge that it had received and fulfilled suspicious orders for overly large quantities of prescription opioids for non-medical purposes.

861. McKesson's failure to maintain effective controls over the distribution of prescription opioids, including by oversupplying prescription opioids and by fulfilling and failing to identify or report suspicious orders, was a substantial factor in opioids becoming widely available, widely used and misused, resulting in an epidemic of opioid dependency.

862. McKesson's failure to stop the fulfillment of orders that it knew or should have known were suspicious was a substantial factor in opioids becoming widely available and widely used and misused.

863. McKesson's unlawful conduct was a direct and proximate cause of opioids becoming widely available, used, and all too often abused. No third party broke the causal chain between McKesson's wrongful conduct and the resulting harm.

864. But for McKesson's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. McKesson's actions have harmed and will continue to harm many residents throughout Illinois, including opioid users, their families, and their communities at large.

865. The intent of the McKesson's distribution of opioids was to sell more of them. McKesson intended for pharmacies and patients to dispense and fill increasing numbers of prescriptions, and then for that prescription pattern to continue, often at higher and higher doses.

866. The public nuisance and associated financial and economic losses resulting from McKesson's deceptive and unfair conduct were foreseeable to McKesson, which knew or should have known that its conduct would create a public health crisis. As alleged herein, McKesson engaged in widespread deceptive, unfair, and unlawful distribution of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death.

867. A reasonable pharmaceutical distributor in McKesson's position would have foreseen not only a vastly expanded market for opioids, but also the related likely and foreseeable result of its conduct – the widespread problems of opioid addiction and abuse. In fact, McKesson was on notice and aware of signs that pharmacies were dispensing, and health care providers were prescribing, unreasonably high numbers of opioids, and that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

868. McKesson would not be unduly burdened by taking measures, consistent with what state and federal law require, to sufficiently monitor suspicious orders and stem the flood of opioids into the State.

869. The benefits of requiring McKesson to undertake anti-diversion measures include preventing abuse, addiction, and their injurious impacts on the State. The existence of such benefits is demonstrated by the codification of McKesson's obligation to prevent diversion in state and federal law.

870. McKesson's unlawful business practices ultimately generated a new and very profitable circular market – providing both the supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

871. The injuries resulting from McKesson's misconduct described above are severe, including opioid addiction, overdose, and death, as well as increased health care costs and loss of productivity. The State has suffered special injuries different from the general public, including the substantial costs associated with the investigation, monitoring, treatment, policing, and other remediation of the opioid epidemic.

872. McKesson acted without express authority of a statute or law when it engaged in the deceptive and unfair practices described herein.

873. McKesson's conduct was not insubstantial or fleeting; to the contrary, McKesson substantially and unreasonably interfered with public rights, and proximately caused and continues to cause significant injury to the public. McKesson's wrongful conduct is ongoing and persistent, and continues to cause tremendous injury to the public and the State to incur significant costs.

874. The public nuisance – i.e., the opioid epidemic – created, maintained, and perpetuated by McKesson can be abated, and further recurrence of such harm and inconvenience can be abated, by (a) requiring McKesson to implement effective controls and procedures in its supply chains to guard against the diversion of opioids; (b) requiring McKesson to design and operate an adequate system to detect, halt, and report suspicious orders of controlled substances; (c) ceasing the further dissemination of any misleading information about opioids in general; (d) educating prescribers (especially primary care physicians, nurse practitioners, physician assistants, and the most prolific prescribers of opioids), patients, and pharmacies regarding the true risks and

benefits of opioids, including the risk of addiction; (e) educating young people in particular about the risks of addiction; and (f) making overdose reversal drugs widely available so that overdoses are less frequently fatal, among other measures.

875. The State seeks an order that provides for abatement of the public nuisance McKesson has created, enjoins McKesson from further deceptive and unfair conduct, and awards the State the costs associated with abatement of the nuisance and harm to the State in an amount to be determined at trial.

THIRTEENTH CAUSE OF ACITON

PUBLIC NUISANCE (CARDINAL)

876. The State incorporates Paragraphs 1 through 761 above as if set forth in their entirety.

877. A public nuisance is something that negatively affects the public's health, safety, or morals, or causes substantial annoyance, inconvenience, or injury to the public.

878. As acknowledged by the DEA, "the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people" and "[f]ailure to maintain effective controls against diversion is inconsistent with the public interest[.]"

879. Illinois residents have a public right to health, safety, peace, and comfort. Those rights are a matter of great interest and of legitimate concern to the State, which has a duty to protect the health, safety, and well-being of its residents. The Attorney General has the power and authority to bring suit to abate a public nuisance.

880. Cardinal has a duty under the CSA to maintain and implement effective anti-diversion controls, including identifying, reporting, and halting suspicious orders. See 21 U.S.C. §§ 823(b)(1), 1307.74(b). Cardinal is also required to abide by the Illinois Controlled Substance

Act, in which the Illinois General Assembly specifically recognized, "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100.

881. Cardinal also has a duty under the Consumer Fraud Act to refrain from deceptive or unfair practices in the course of trade or commerce. Cardinal unlawfully violated this duty.

882. As described in detail above, Cardinal's unlawful practices substantially and unreasonably interfered with the public rights to health, safety, comfort, and peace. For example, as a result of Cardinal's conduct:

a. Opioid use, abuse, and overdose deaths have increased throughout Illinois;

b. Buildings and public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to overprescribing, and the foreseeable failure to safely dispose of opioids;

c. The greater demand for emergency services, law enforcement, addiction treatment, and social services has placed an unreasonable burden on State and local resources;

d. Expanding the market for prescription opioids to primary care patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury;

e. Additional illicit markets in other opiates have been created, particularly for heroin. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process;

f. Health care costs have increased for individuals, families, and the State; and

g. Health care providers and pharmacies who were profitable to Cardinal but harmful to the public continued prescribing and dispensing increasing numbers of opioids throughout the State in light of Cardinal's failure to establish and implement effective abuse and diversion monitoring policies.

883. Cardinal controlled and controls the "instrumentality" of the nuisance – its distribution of addictive opioid medications – failing to appropriately monitor, prevent, and report the potential abuse and diversion of opioids.

884. Cardinal occupies a pivotal and unique position within the distribution chain and possesses the information, knowledge, skill, and sophistication required of it by federal and state laws to maintain effective controls on the distribution of prescription opioids and to identify, report, and refuse to fill suspicious orders of opioid pharmaceuticals.

885. Cardinal, individually and in concert with others, unlawfully provided an oversupply of prescription opioids within the State, thus substantially contributing to the over-prescription and overuse of prescription opioids, including by supplying pill mills and other providers or prescribers who were engaged in an illegal market for the sale of opioids for non-medical purposes.

886. Cardinal willfully turned a blind eye and concealed and/or failed to use the knowledge that it had received and fulfilled suspicious orders for overly large quantities of prescription opioids for non-medical purposes.

887. In light of the information, knowledge, skill, and sophistication it possessed, Cardinal knew or should have known that it was oversupplying the State with prescription opioids, including by supplying pill mills and other providers or prescribers who were engaged in an illegal market for the sale of opioids for non-medical purposes. The knowing and/or negligent oversupply by Cardinal, individually and in concert with others, has fueled addiction, misuse, and diversion of the drugs for improper purposes.

888. In light of the information, knowledge, skill, and sophistication it possessed, Cardinal knew or should have known that orders it received and filled for overly large quantities of

prescription opioids were suspicious and that these orders should have been identified and reported, and not fulfilled. Cardinal willfully turned a blind eye and concealed and/or failed to use the knowledge that it had received and fulfilled suspicious orders for overly large quantities of prescription opioids for non-medical purposes.

889. Cardinal's failure to maintain effective controls over the distribution of prescription opioids, including by oversupplying prescription opioids and by fulfilling and failing to identify or report suspicious orders, was a substantial factor in opioids becoming widely available, widely used and misused, resulting in an epidemic of opioid dependency.

890. Cardinal's failure to stop the fulfillment of orders that it knew or should have known were suspicious was a substantial factor in opioids becoming widely available, widely used and misused.

891. Cardinal's unlawful conduct was a direct and proximate cause of opioids becoming widely available, used, and all too often abused. No third party broke the causal chain between Cardinal's wrongful conduct and the resulting harm.

892. But for Cardinal's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. Cardinal's actions have harmed and will continue to harm many residents throughout Illinois, including opioid users, their families, and their communities at large.

893. The intent of the Cardinal's distribution of opioids was to sell more of them. Cardinal intended for pharmacies and patients to dispense and fill increasing numbers of prescriptions, and then for that prescription pattern to continue, often at higher and higher doses.

894. The public nuisance and associated financial and economic losses resulting from Cardinal's deceptive and unfair conduct were foreseeable to Cardinal, which knew or should

have known that its conduct would create a public health crisis. As alleged herein, Cardinal engaged in widespread deceptive, unfair, and unlawful distribution of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death.

895. A reasonable pharmaceutical distributor in Cardinal's position would have foreseen not only a vastly expanded market for opioids, but also the related likely and foreseeable result of its conduct – the widespread problems of opioid addiction and abuse. In fact, Cardinal was on notice and aware of signs that pharmacies were dispensing, and health care providers were prescribing, unreasonably high numbers of opioids, and that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

896. Cardinal would not be unduly burdened by taking measures, consistent with what state and federal law require, to sufficiently monitor suspicious orders and stem the flood of opioids into the State.

897. The benefits of requiring Cardinal to undertake anti-diversion measures include preventing abuse, addiction, and their injurious impacts on the State. The existence of such benefits is demonstrated by the codification of Cardinal's obligation to prevent diversion in state and federal law.

898. Cardinal's unlawful business practices ultimately generated a new and very profitable circular market – providing both the supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

899. The injuries resulting from Cardinal's misconduct described above are severe, including opioid addiction, overdose, and death, as well as increased health care costs and loss of productivity. The State has suffered special injuries different from the general public, including

the substantial costs associated with the investigation, monitoring, treatment, policing, and other remediation of the opioid epidemic.

900. Cardinal acted without express authority of a statute or law when it engaged in the deceptive and unfair practices described herein.

901. Cardinal's conduct was not insubstantial or fleeting; to the contrary, Cardinal substantially and unreasonably interfered with public rights, and proximately caused and continues to cause significant injury to the public. Cardinal's wrongful conduct is ongoing and persistent, and continues to cause tremendous injury to the public and the State to incur significant costs.

902. The public nuisance – i.e., the opioid epidemic – created, maintained, and perpetuated by Cardinal can be abated, and further recurrence of such harm and inconvenience can be abated, by (a) requiring Cardinal to implement effective controls and procedures in its supply chains to guard against the diversion of opioids; (b) requiring Cardinal to design and operate an adequate system to detect, halt, and report suspicious orders of controlled substances; (c) ceasing the further dissemination of any misleading information about opioids in general; (d) educating prescribers (especially primary care physicians, nurse practitioners, physician assistants, and the most prolific prescribers of opioids), patients, and pharmacies regarding the true risks and benefits of opioids, including the risk of addiction; (e) educating young people in particular about the risks of addiction; and (f) making overdose reversal drugs widely available so that overdoses are less frequently fatal, among other measures.

903. The State seeks an order that provides for abatement of the public nuisance Cardinal has created, enjoins Cardinal from further deceptive and unfair conduct, and awards the State the

costs associated with abatement of the nuisance and harm to the State in an amount to be determined at trial.

FOURTEENTH CAUSE OF ACTION

PUBLIC NUISANCE (AMERISOURCEBERGEN)

904. The State incorporates Paragraphs 1 through 761 above as if set forth in their entirety.

905. A public nuisance is something that negatively affects the public's health, safety, or morals, or causes substantial annoyance, inconvenience, or injury to the public.

906. As acknowledged by the DEA, "the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people" and "[f]ailure to maintain effective controls against diversion is inconsistent with the public interest[.]"

907. Illinois residents have a public right to health, safety, peace, and comfort. Those rights are a matter of great interest and of legitimate concern to the State, which has a duty to protect the health, safety, and well-being of its residents. The Attorney General has the power and authority to bring suit to abate a public nuisance.

908. AmerisourceBergen has a duty under the CSA to maintain and implement effective anti-diversion controls, including identifying, reporting, and halting suspicious orders. See 21 U.S.C. §§ 823(b)(1), 1307.74(b). AmerisourceBergen is also required to abide by the Illinois Controlled Substance Act, in which the Illinois General Assembly specifically recognized, "the rising incidence in the abuse of drugs and other dangerous substances and its resultant damage to the peace, health, and welfare of the citizens of Illinois." 720 ILCS 570/100.

909. AmerisourceBergen also has a duty under the Consumer Fraud Act to refrain from deceptive or unfair practices in the course of trade or commerce. AmerisourceBergen unlawfully violated this duty.

910. As described in detail above, AmerisourceBergen's unlawful practices substantially and unreasonably interfered with the public rights to health, safety, comfort, and peace. For example, as a result of AmerisourceBergen's conduct:

a. Opioid use, abuse, and overdose deaths have increased throughout Illinois;

b. Buildings and public spaces have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe. In addition, family medicine cabinets became outlets for diversion and abuse due to overprescribing, and the foreseeable failure to safely dispose of opioids;

c. The greater demand for emergency services, law enforcement, addiction treatment, and social services has placed an unreasonable burden on State and local resources;

d. Expanding the market for prescription opioids to primary care patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a wave of addiction, abuse, and injury;

e. Additional illicit markets in other opiates have been created, particularly for heroin. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin as an alternative, fueling a new heroin epidemic in the process;

f. Health care costs have increased for individuals, families, and the State; and

g. Health care providers and pharmacies who were profitable to AmerisourceBergen but harmful to the public continued prescribing and dispensing increasing numbers of opioids throughout the State in light of AmerisourceBergen's failure to establish and implement effective abuse and diversion monitoring policies.

911. AmerisourceBergen controlled and controls the "instrumentality" of the nuisance – its distribution of addictive opioid medications – failing to appropriately monitor, prevent, and report the potential abuse and diversion of opioids.

912. AmerisourceBergen occupies a pivotal and unique position within the distribution chain and possesses the information, knowledge, skill, and sophistication required of it by federal and state laws to maintain effective controls on the distribution of prescription opioids and to identify, report, and refuse to fill suspicious orders of opioid pharmaceuticals.

913. AmerisourceBergen, individually and in concert with others, unlawfully provided an oversupply of prescription opioids within the State, thus substantially contributing to the over-prescription and overuse of prescription opioids, including by supplying pill mills and other providers or prescribers who were engaged in an illegal market for the sale of opioids for non-medical purposes.

914. AmerisourceBergen willfully turned a blind eye and concealed and/or failed to use the knowledge that it had received and fulfilled suspicious orders for overly large quantities of prescription opioids for non-medical purposes.

915. In light of the information, knowledge, skill, and sophistication it possessed, AmerisourceBergen knew or should have known that it was oversupplying the State with prescription opioids, including by supplying pill mills and other providers or prescribers who were engaged in an illegal market for the sale of opioids for non-medical purposes. The knowing and/or negligent oversupply by AmerisourceBergen, individually and in concert with others, has fueled addiction, misuse, and diversion of the drugs for improper purposes.

916. In light of the information, knowledge, skill, and sophistication it possessed, AmerisourceBergen knew or should have known that orders it received and filled for overly large quantities of prescription opioids were suspicious and that these orders should have been identified and reported, and not fulfilled. AmerisourceBergen willfully turned a blind eye and

concealed and/or failed to use the knowledge that it had received and fulfilled suspicious orders for overly large quantities of prescription opioids for non-medical purposes.

917. AmerisourceBergen's failure to maintain effective controls over the distribution of prescription opioids, including by oversupplying prescription opioids and by fulfilling and failing to identify or report suspicious orders, was a substantial factor in opioids becoming widely available, widely used and misused, resulting in an epidemic of opioid dependency.

918. AmerisourceBergen's failure to stop the fulfillment of orders that it knew or should have known were suspicious was a substantial factor in opioids becoming widely available, widely used and misused.

919. AmerisourceBergen's unlawful conduct was a direct and proximate cause of opioids becoming widely available, used, and all too often abused. No third party broke the causal chain between AmerisourceBergen's wrongful conduct and the resulting harm.

920. But for AmerisourceBergen's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. AmerisourceBergen's actions have harmed and will continue to harm many residents throughout Illinois, including opioid users, their families, and their communities at large.

921. The intent of the AmerisourceBergen's distribution of opioids was to sell more of them. AmerisourceBergen intended for pharmacies and patients to dispense and fill increasing numbers of prescriptions, and then for that prescription pattern to continue, often at higher and higher doses.

922. The public nuisance and associated financial and economic losses resulting from AmerisourceBergen's deceptive and unfair conduct were foreseeable to AmerisourceBergen,

which knew or should have known that its conduct would create a public health crisis. As alleged herein, AmerisourceBergen engaged in widespread deceptive, unfair, and unlawful distribution of opioids despite knowing that opioids carried serious risks of addiction, injury, overdose, and death.

923. A reasonable pharmaceutical distributor in AmerisourceBergen's position would have foreseen not only a vastly expanded market for opioids, but also the related likely and foreseeable result of its conduct – the widespread problems of opioid addiction and abuse. In fact, AmerisourceBergen was on notice and aware of signs that pharmacies were dispensing, and health care providers were prescribing, unreasonably high numbers of opioids, and that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

924. AmerisourceBergen would not be unduly burdened by taking measures, consistent with what state and federal law require, to sufficiently monitor suspicious orders and stem the flood of opioids into the State.

925. The benefits of requiring AmerisourceBergen to undertake anti-diversion measures include preventing abuse, addiction, and their injurious impacts on the State. The existence of such benefits is demonstrated by the codification of AmerisourceBergen's obligation to prevent diversion in state and federal law.

926. AmerisourceBergen's unlawful business practices ultimately generated a new and very profitable circular market – providing both the supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand of users to buy more.

927. The injuries resulting from AmerisourceBergen's misconduct described above are severe, including opioid addiction, overdose, and death, as well as increased health care costs and loss of productivity. The State has suffered special injuries different from the general public, including

the substantial costs associated with the investigation, monitoring, treatment, policing, and other remediation of the opioid epidemic.

928. AmerisourceBergen acted without express authority of a statute or law when it engaged in the deceptive and unfair practices described herein.

929. AmerisourceBergen's conduct was not insubstantial or fleeting; to the contrary, AmerisourceBergen substantially and unreasonably interfered with public rights, and proximately caused and continues to cause significant injury to the public. AmerisourceBergen's wrongful conduct is ongoing and persistent, and continues to cause tremendous injury to the public and the State to incur significant costs.

930. The public nuisance – i.e., the opioid epidemic – created, maintained, and perpetuated by AmerisourceBergen can be abated, and further recurrence of such harm and inconvenience can be abated, by (a) requiring AmerisourceBergen to implement effective controls and procedures in its supply chains to guard against the diversion of opioids; (b) requiring AmerisourceBergen to design and operate an adequate system to detect, halt, and report suspicious orders of controlled substances; (c) ceasing the further dissemination of any misleading information about opioids in general; (d) educating prescribers (especially primary care physicians, nurse practitioners, physician assistants, and the most prolific prescribers of opioids), patients, and pharmacies regarding the true risks and benefits of opioids, including the risk of addiction; (e) educating young people in particular about the risks of addiction; and (f) making overdose reversal drugs widely available so that overdoses are less frequently fatal, among other measures.

931. The State seeks an order that provides for abatement of the public nuisance AmerisourceBergen has created, enjoins AmerisourceBergen from further deceptive and unfair

conduct, and awards the State the costs associated with abatement of the nuisance and harm to the State in an amount to be determined at trial.

PRAYER FOR RELIEF

Wherefore, the State prays for the following relief:

A. Finding that Defendants violated Section 2 of the Consumer Fraud Act, 815 ILCS 505/2, by engaging in unlawful acts and practices including, but not limited to, the unlawful acts and practices alleged herein;

B. Permanently enjoining the Defendants from engaging in the unfair and/or deceptive acts or practices described herein;

C. Ordering Defendants to pay a civil penalty of $50,000 per deceptive or unfair act or practice, and an additional amount of $50,000 for each act or practice found to have been committed with the intent to defraud, all as provided in Section 7 of the Consumer Fraud Act, 815 ILCS 505/7;

D. Assessing an additional civil penalty in the amount of $10,000 per violation found by the Court to have been committed by the Defendants against a person 65 years of age and older as provided in Section 7(c) of the Consumer Fraud Act, 815 ILCS 505/7(c);

E. Disgorging all revenues, profits, and gains achieved in whole or in part through the deceptive and unfair acts or practices complained of herein;

F. Requiring full restitution be made to consumers who were harmed by Defendants' deceptive and unfair acts or practices;

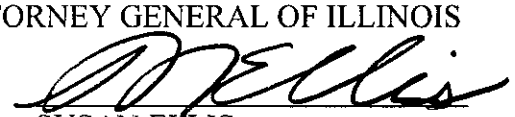
G. Requiring the Defendants to pay all costs for the prosecution and investigation of this action, as provided by Section 10 of the Consumer Fraud Act, 815 ILCS 505/10;

H. An order requiring Defendants to abate the public nuisance that they created and

compensate the State for costs associated with its abatement efforts; and

I. Providing such other and further relief as justice and equity may require.

THE PEOPLE OF THE STATE OF
ILLINOIS, by KWAME RAOUL
ATTORNEY GENERAL OF ILLINOIS

BY: 
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