UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

The Leech Lake Band of Ojibwe, Plaintiff, v. Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation, Defendants.	Case No. **COMPLAINT** **Jury Trial Demanded**

Plaintiff The Leech Lake Band of Ojibwe ("Plaintiff"), an Ojibwe band of the Minnesota Chippewa Tribe, brings this action in the exercise of its authority and on behalf of the Leech Lake Band in its proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of all Leech Lake members against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively "Defendants") and alleges as follows:

I. INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent because of Defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.[1] Such economic damages were

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

foreseeable to Defendants and were sustained because of Defendants' intentional and/or unlawful actions and omissions.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[2]

3. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[3]

4. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids and turned patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

5. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

[2] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).
[3] *See* Robert M. Califf et al., A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016).

II. PARTIES

A. PLAINTIFF THE LEECH LAKE BAND OF OJIBWE

6. Plaintiff Leech Lake Band of Ojibwe (the "Band" or "Plaintiff") is one of six bands located in Minnesota making up the federally recognized sovereign Indian nation, the Minnesota Chippewa Tribe (the "Tribe"). Under the Minnesota Chippewa Constitution of 1964, the Tribe and the Bands are governed by a Tribal Executive Committee and each of the six bands is governed by a Reservation Business Committee. The Band is governed by the Leech Lake Reservation Business Committee. The Band's reservation is located in north central Minnesota, in the counties of Beltrami, Cass, Hubbard, and Itasca (the "Reservation"). Members of the Band affected by the opioid crisis described in this complaint live on the Band's reservation, as well as, throughout Minnesota.

7. The distribution and diversion of opioids into Minnesota ("the State"), and into the Reservation and surrounding areas (collectively, "Plaintiff's Community"), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

8. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical

conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; (5) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered directly, by the Plaintiff.

9. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

B. DEFENDANTS.

1. Manufacturer Defendants

10. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have designed, manufactured, packaged, , supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs.

11. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut. PURDUE PHARMA L.P., PURDUE PHARMA INC. AND PURDUE FREDERICK COMPANY are collectively referred to herein as "Purdue."

12. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual

nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

13. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation which is registered to do business in Minnesota and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

14. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[4] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[5] In 2008, Cephalon pled guilty to a criminal violation

[4] *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.
[5] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[6]

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

16. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[7] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora®.[8] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the

[6] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-cv-860.html.
[7] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last visited Aug. 21, 2017).
[8] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are collectively referred to as "Cephalon."

17. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are collectively referred to as "Janssen."

18. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

19. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo."

20. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

21. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to

Actavis, Inc. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is registered to do business with the Minnesota Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are collectively referred to as "Actavis."

22. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

23. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware and licensed to do business in Minnesota.

Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc. Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt."

24. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017 Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

2. Distributor Defendants

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

26. McKESSON CORPORATION ("McKesson") at all relevant times, operated as a licensed pharmacy wholesaler in Minnesota. McKesson is registered with the Minnesota Secretary of State as a Delaware corporation. McKesson has its principal place of business located in San Francisco, California. McKesson operates distribution centers in Minnesota, including in Maple Grove, Minnesota.

27. CARDINAL HEALTH, INC. ("Cardinal") is registered with the Minnesota Secretary of State as a Delaware corporation, with its principal office located in Dublin, Ohio.

28. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") at all relevant times, operated as a licensed pharmacy wholesaler in Minnesota. AmerisourceBergen is registered with the Minnesota Secretary of State as a Delaware corporation. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania. AmerisourceBergen operates distribution centers in Minnesota, including in Shakopee, Minnesota.

29. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA[9] nor the wholesale distributors[10] will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.

[9] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

[10] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN (Document 93) (filed Nov. 2, 2016) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

30. Collectively, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into our community. Plaintiff names each of the "Big 3" herein as defendants and places the industry on notice that the Plaintiff is acting to abate the public nuisance plaguing the community. Plaintiff will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

III. JURISDICTION & VENUE

31. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1362 based upon the federal claims asserted under 15 U.S.C. § 1051 et seq. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

32. The Band has inherent sovereignty over unlawful conduct that takes place on, or has a direct impact on, land that constitutes Indian country within the Band. Federal

law recognizes the Band's and the Tribe's authority over its members and its territory, specifically the authority to promote the autonomy and the health and welfare of the Band. Defendants engaged in activities and conduct that takes place on or has a direct impact on, land that constitutes Indian country within the Band.

33. This Court has personal jurisdiction over Defendants because they conduct business in Minnesota, as well as Plaintiff's Community, and purposefully direct or directed their actions toward Minnesota, consented to be sued in Minnesota by registering an agent for service of process, consensually submitted to the jurisdiction of Minnesota when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Minnesota necessary to constitutionally permit the Court to exercise jurisdiction.

IV. FACTUAL BACKGROUND

A. THE OPIOID EPIDEMIC

1. The National Opioid Epidemic

34. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.[11]

35. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[12]

[11] *See* Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).
[12] Katherine M. Keyes at al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

36. Despite having only 4.6% of the world's population, the United States consumes four-fifths of the world opioid supply.[13]

37. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

> 1. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
> 2. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
> 3. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
> 4. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
> 5. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
> 6. Almost 5,500 people start to misuse prescription painkillers every day.[14]

[13] Opioids: Preventing and Addressing Prescription Drug Abuse, State of Minnesota, Office of the Attorney General, https://www.leg.state.mn.us/docs/2017/other/170004.pdf (last visited Nov. 11, 2017), at 8.

[14] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

38. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.[15]

39. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.[16]

40. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[17]

41. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[18]

42. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past misuse of prescription opioids is the***

[15] *See* Califf et al., *supra* note 3.
[16] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.
[17] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Today's Heroin Epidemic, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).
[18] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.[19]

43. The societal costs of prescription drug abuse are "huge."[20]

44. Across the nation, local governments are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids. [21]

45. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[22] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[23]

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[19] *See* Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014,* 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).
[20] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016,at *10 [hereinafter Brief of HDMA].
[21] Opioid Crisis, NIH, National Institute on Drug Abuse ("Opioid Crisis, NIH") (available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis) (last visited Sept. 19, 2017) (citing Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Weekly Report 1445 (Dec. 30, 2016)).
[22] Opioid Crisis, NIH.
[23] *Id.* (citing Curtis S. Florence et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 Medical Care 901 (2016)).

46. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[24]

47. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[25]

48. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are "everywhere" and mistaken as candy.[26]

49. In 2016, the President of the United States declared an opioid and heroin epidemic.[27] In 2017, the President of the United States declared the opioid crisis a public health emergency.[28]

50. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.[29] Meanwhile, the

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[24] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Weekly Report 1445 (Dec. 30, 2016).
[25] *See* Volkow & McLellan*, supra* note 2.
[26] Julie Turkewitz, *"The Pills are Everywhere": How the Opioid Crisis Claims Its Youngest Victims,* N.Y. Times, Sept. 20, 2017 ("'It's a cancer,' said [grandmother of dead one-year old], of the nation's opioid problem, 'with tendrils that are going everywhere.'").
[27] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").
[28] President Donald J. Trump is Taking Action Drub Addiction and the Opioid Crisis, https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis (October 26, 2017).
[29] *See* Presidential Memorandum—Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://www.gpo.gov/fdsys/pkg/DCPD-

manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

51. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to the national, state, and local opioid epidemic.

2. The Minnesota Opioid Epidemic

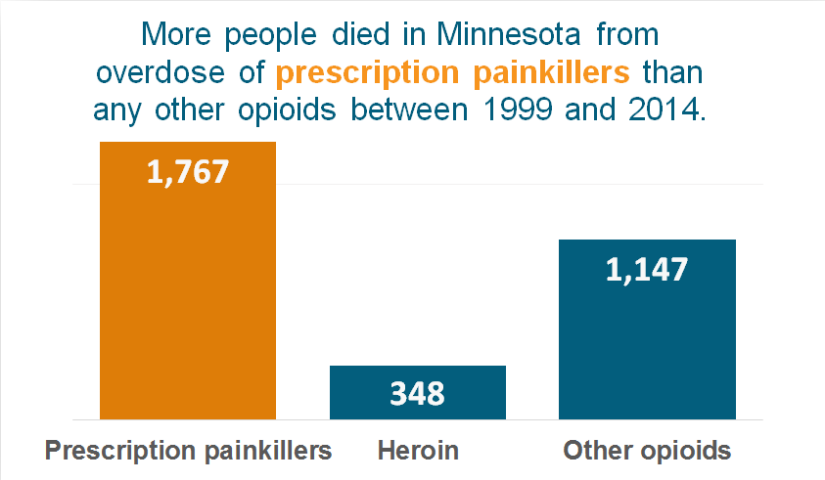
52. Minnesota has been hard hit by the opioid epidemic. The state has undertaken large expenditures to attempt to undue the harm caused by Defendants and their role in creating and perpetuating the opioid crisis.[30]

53. The Defendants' failure to adequately safeguard prescription opioids has been acutely felt in Minnesota, where overdose deaths due to prescription painkillers have outpaced both heroin and other opioid overdoses, between 1999 and 2014.[31]

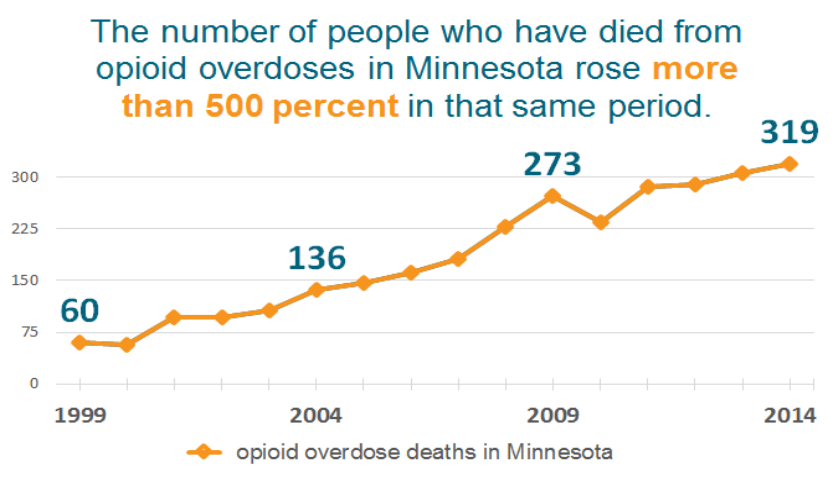
201500743/pdf/DCPD-201500743.pdf.

[30] Minnesota's Drug Overdose Deaths Continued to Rise in 2016 ("Minnesota's Drug Overdose Deaths"), Minnesota Department of Health (Sept. 7, 2017), http://www.health.state.mn.us/news/pressrel/2017/opioid090717.html (noting Minnesota's proposed $42 million dollar investment in opioid addiction prevention and treatment).

[31] Here's Why Minnesota Has a Big Problem with Opioid Overdoses, Jon Collins, Minnesota Public Radio, https://www.mprnews.org/story/2016/04/18/opioid-overdose-epidemic-explained.



54. Minnesota has experienced a more than 500% increase in opioid overdoses over the same period of time.[32]

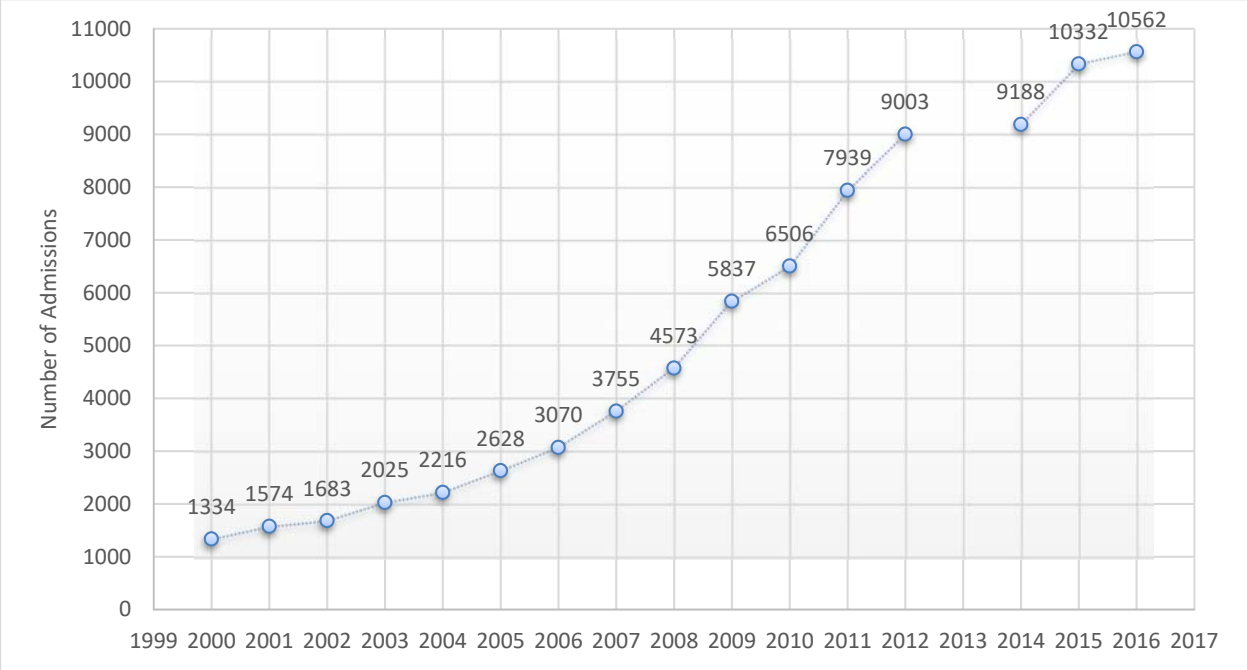


55. Since 2014, overdose rates in Minnesota have continued to rise. The state experienced a 9.2% increase from 2015 to 2016, and the overdose rate in 2016 was almost

[32] *Id.*

six times the rate in 2000. Over half of the overdoses in 2016 were opioid related—up 12% from 2015.[33]

56. In addition to confronting the increasing number of overdoses, Minnesota has likewise seen a staggering increase in the number of its residents admitted to drug treatment facilities for opioid addiction treatment, increasing almost tenfold from 2000 to 2016.[34]



57. It Minnesota, the costs related to the opioid epidemic exceed 375 million dollars, accounting for a $69 per capita health care cost for opioid abuse alone.[35]

[33] Minnesota's Drug Overdose Deaths, *supra* note 30.
[34] *See generally* Substance Abuse in Minnesota, Minnesota Department of Human Services, https://www.sumn.org.
[35] Health Care Costs from Opioid Abuse: A State-by-State Analysis, Matrix Global Advisors, LLC, (April 2015), https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf.

3. The Native American Opioid Crisis Nationally and in Minnesota

58. Native Americans have been particularly hard hit by the opioid epidemic. The CDC reported that in 2012, 1 in 10 native person (over the age of 12) used prescription pain medicine for nonprescription purposes, compared with 1 in 20 whites and 1 in 30 African-Americans. Similarly, CDC data shows that in 2014 Native Americans had the highest rate per 100,000 people of opioid overdoses. [36]

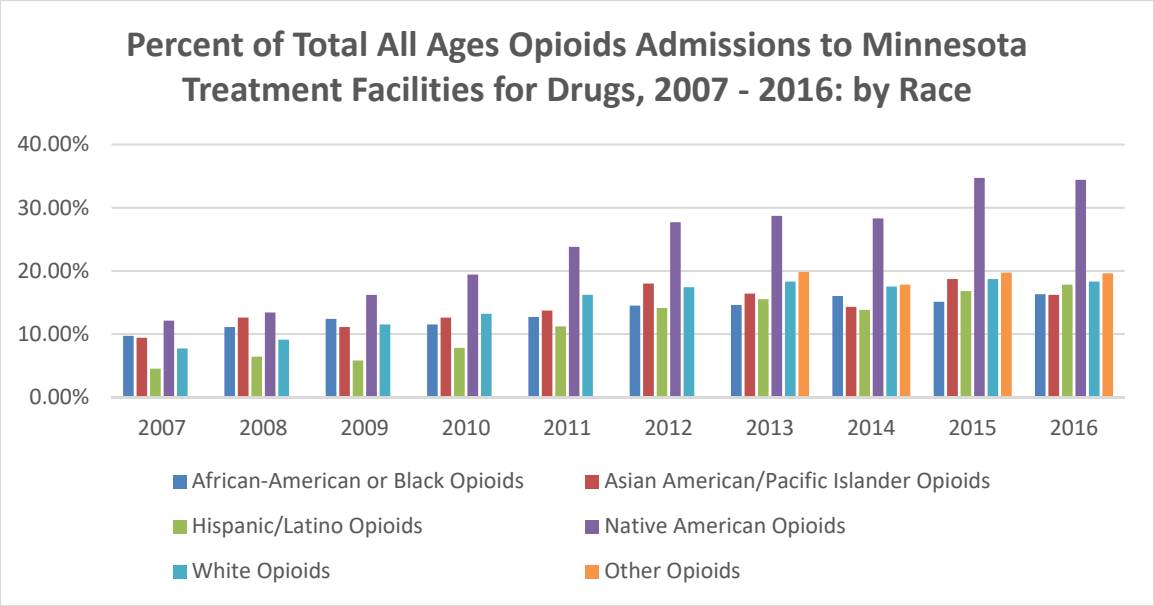
59. Native Americans in Minnesota have been especially vulnerable to the opioid crisis. Minnesota ranks first among all state for overdose deaths of Native persons.[37]

60. Native persons account for a larger percentage of opioid treatment admissions than any other racial group in Minnesota, and that trend is increasing.[38]

[36] National Congress of American Indians, Reflecting on a Crisis Curbing Opioid Abuse in Communities, (Oct. 2016), http://www.ncai.org/policy-research-center/research-data/prc-publications/Opioid_Brief.pdf.

[37] Statement by Chief Executive Melanie Benjamin, Oversight Hearing on Examining the True Costs of Alcohol and Drug Abuse in Native Communities, Senate Committee on Indian Affairs (July 29, 2015), https://www.indian.senate.gov/sites/default/files/upload/files/072915Testimony%20Melanie%20Benjamin.pdf.

[38] *See generally* Substance Abuse in Minnesota, Minnesota Department of Human Services, http://www.sumn.org.



61. Similarly, Native persons are at a greater risk of being diagnosed with maternal opiate dependency.[39] Relatedly, of all babies born addicted to opiates in Minnesota, 28% are Native persons.[40]

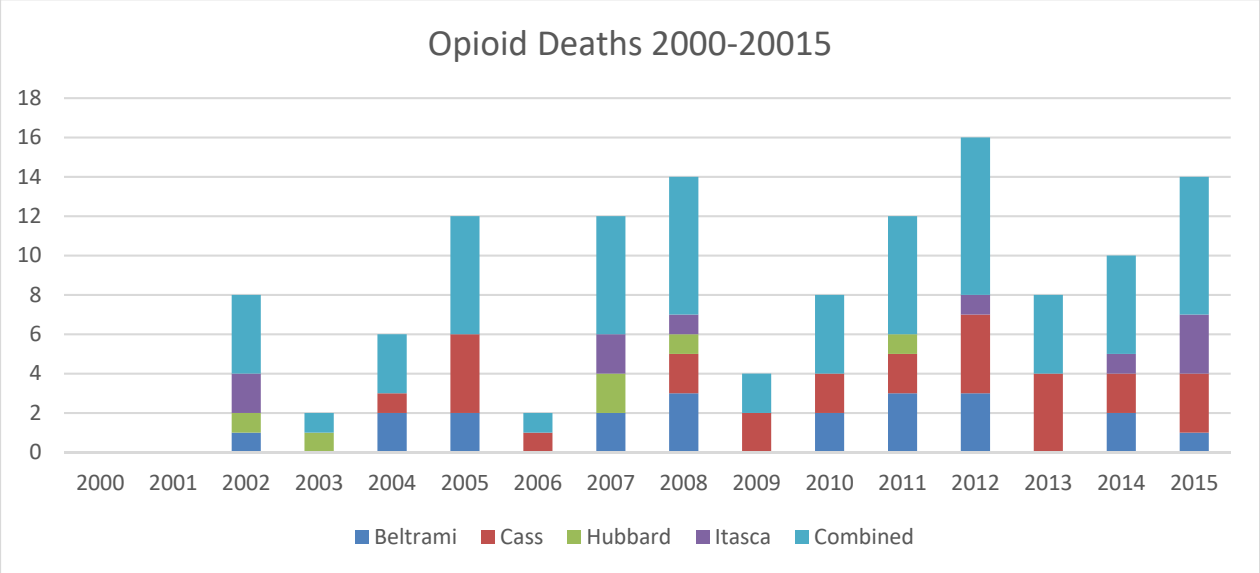
4. The Leech Lake Ojibwe and Surrounding Counties Opioid Crisis.

62. As noted above, the Reservation sits in four adjacent counties: Beltrami, Cass, Hubbard, and Itasca.

[39] Minnesota State Targeted Response to the Opioid Crisis: Project Narrative, Minnesota Department of Human Services (April 2017), https://mn.gov/dhs/assets/mn-opioid-str-project-narrative-april-2017_tcm1053-289624.pdf.

[40] Statement by Chief Executive Melanie Benjamin, Oversight Hearing on Examining the True Costs of Alcohol and Drug Abuse in Native Communities, Senate Committee on Indian Affairs (July 29, 2015), https://www.indian.senate.gov/sites/default/files/upload/files/072915Testimony%20Melanie%20Benjamin.pdf.

63. In 2000 there were no deaths in the four-county area caused by opioids. However, over the past 15 years those number have tended to increase, and 2015 there were 7 opioid deaths in the four-county area where the Reservation sits.[41]

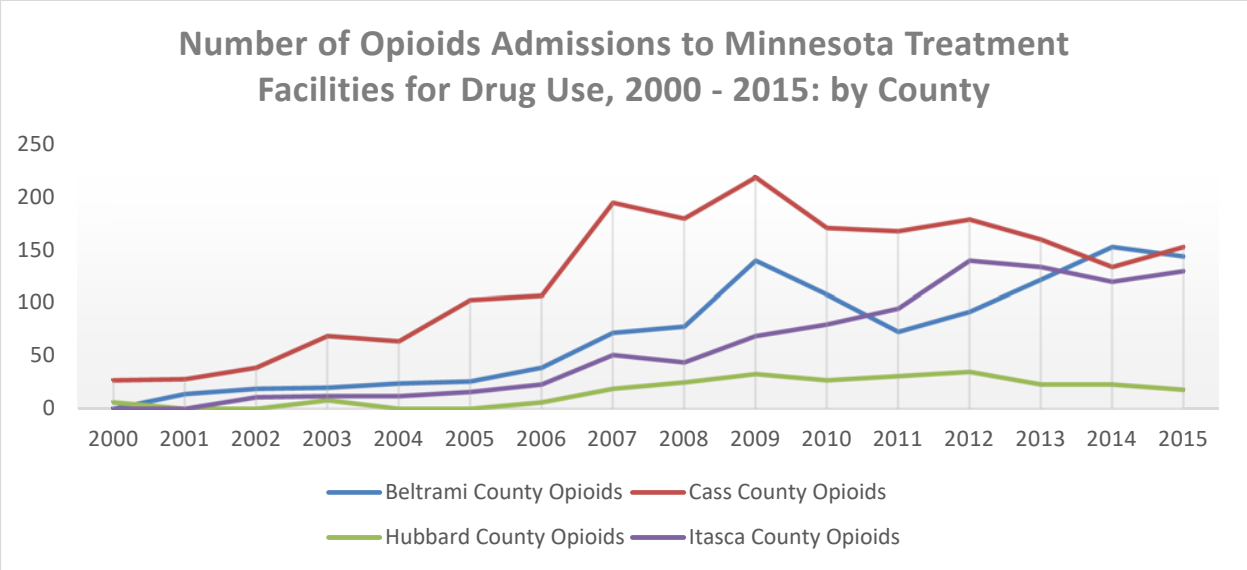


64. In an effort to combat the effects of the opioid crisis on its members, Plaintiff operates an Opioid Treatment Program, with a mission "to provide community based,

[41] *See generally* Substance Abuse in Minnesota, Minnesota Department of Human Services, http://www.sumn.org. *See also* Minnesota Department of Health: Injury and Violence Prevention Unit, Drug overdose deaths among Minnesota residents: 2000-2015 report Available at: http://www.health.state.mn.us/divs/healthimprovement/content/documents/2015OpioidDeathReport.pdf.

culturally focused substance addiction recovery services that will promote holistic health and a drug free lifestyle for our clients, their families, and our communities."[42]

65. During this same time period, a similar upward trend can be seen in each County for residents admitted to treatment facilities for treatment of opioid addiction.[43]



66. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff has expended, and will continue to expend resources in an effort to manage the opioid crisis and consequences thereof.

B. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

67. The opioid epidemic did not happen by accident. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used

[42] National Congress of American Indians, Reflecting on a Crisis Curbing Opioid Abuse in Communities, (Oct. 2016), http://www.ncai.org/policy-research-center/research-data/prc-publications/Opioid_Brief.pdf.

[43] Substance Abuse in Minnesota, Minnesota Department of Human Services, http://www.sumn.org.

short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

68. Each Manufacturer Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

69. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse

and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

70. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

71. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[44] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[45]This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand).

[44] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine,* Fortune, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drug Makers Hooked on $10bn Opioid Habit,* Fin. Times, Aug. 10, 2016, https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.
[45] Letter of Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), *at* http://turnthetiderx.org/.

And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

72. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids

73. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the State, including in Plaintiff's Community. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's Community.

74. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the State, including in Plaintiff's Community, as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Manufacturer

Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

75. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

i. Direct Marketing

76. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

77. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional

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

78. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of $168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

79. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing affects prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

80. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been

distributing promotional materials that "minimize [] the risks associated with Kadian and misleadingly suggest [] that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."[46]

ii. Indirect Marketing

81. The Manufacturer Defendants' indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

82. The Manufacturer Defendants deceptively marketed opioids in the State and Plaintiff's Community through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment

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

guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

83. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

84. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors who served as KOLS, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and that the compassionate treatment of pain required opioids.

85. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions include contributing the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promote prescribing practices which have worsened the opioid crisis.

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

87. Defendants used numerous KOLs, including many of the same ones.

88. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from

Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

89. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[47]

90. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them

[47] Good Morning America (ABC television broadcast Aug. 30, 2010).

overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[48] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[49]

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

92. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

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[48] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[49] *Id.*

93. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

94. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Minnesota, including doctors treating members of Plaintiff's Community.[50]

95. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but

[50] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[51] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[52]

96. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

[51] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).
[52] John Fauber, Painkiller Boom Fueled by Networking, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

97. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

98. Defendants Cephalon, Endo, Janssen, and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[53]

99. The most prominent of the Manufacturer Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients,

[53] *See generally* Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dept. of Health and Human Servs., May 5, 2015, https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

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

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

101. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue

told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

102. Plaintiff is informed, and believes, that on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

103. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[54]

104. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

[54] Charles Ornstein & Tracy Weber, Senate Panel Investigates Drug Companies' Ties to Pain Groups, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

105. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

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

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

108. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain

and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[55]

109. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[56] Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

110. At least fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of

[55] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).
[56] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

past abuse histories.[57] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiff's Community during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants financial support to members of the panel.

111. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on

[57] *Id.*

opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

2. The Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids

i. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

112. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

113. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint.

Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use in the State and Plaintiff's Community and each continues to fail to correct its past misrepresentations.

114. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

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

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.[58]

c. Endo sponsored a website, "Pain Knowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

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

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009),

[58] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

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

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[59]

h. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon in the State and Plaintiff's Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[60]

115. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[61] The 2016 CDC Guideline

[59] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[60] Brief of the American Pain Foundation (APF), the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

[61] Deborah Dowell et al., CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[62]

116. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[63]

117. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care

[62] *Id.* at 2, 25.

[63] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

outpatient centers meeting the clinical criteria for an opioid use disorder."[64] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in this State.

118. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

119. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

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

[64] Assurance of Discontinuance, In re Endo Health Solutions Inc. and Endo Pharm. Inc. (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

true addiction.[65] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[66]

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

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

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

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

120. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

[65] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) 62.
[66] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

121. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

122. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."[67]

123. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.[68]

124. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[69]

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[67] 2016 CDC Guideline, *supra* note 55, at 11.
[68] *Id.* at 26.
[69] APF, *Policymaker's Guide*, *supra* note 53, at 32.

125. A fifth category of false, deceptive, and unfair statements the Manufacturer Defendants made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[70] This publication is still available online.

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

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."[71]

[70] APF, *Treatment Options*, *supra* note 52, at 12.

[71] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

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

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

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.[72]

h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.[73]

j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[74]

126. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at

[72] APF, *Policymaker's Guide*, *supra* note53, at 32.
[73] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited Nov. 21, 2017).
[74] Brief of APF, *supra* note 54, at 9.

higher opioid dosage."[75] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[76] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[77] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[78]

127. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

128. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[79] Also troubling, Opana ER can be prepared for snorting using commonly

[75] 2016 CDC Guidelines, *supra* note 55, at 22-23.
[76] *Id.* at 23-24.
[77] *Id.* at 21.
[78] *Id*. at 16.
[79] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

available methods and "readily prepared for injection."[80] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[81] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

ii. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs.

129. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[82] The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

130. Some illustrative examples of the Manufacturer Defendants' false claims are:

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients

[80] *Id*. at 6.
[81] *Id*. at 6, n.21.
[82] *Id.* at 15.

to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

f. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."[83] This publication is still available online.

h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated

[83] APF, *Treatment Options*, *supra* note 52.

NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[84] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

k. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[85] The Policymaker's Guide was originally published in 2011.

l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

131. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

132. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience

[84] *See, e.g.,* NIPC, Persistent Pain and the Older Patient (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.
[85] APF, *Policymaker's Guide*, *supra* note 53, at 29.

. . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[86] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

133. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[87] Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is

[86] Letter from Thomas Abrams to Doug Boothe, *supra* note 40.
[87] 2016 CDC Guideline, *supra* note 55, at 12.

because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

134. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

135. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting

> medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.[88]

136. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.[89] Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are *opioid-tolerant,* meaning those patients who take a regular, daily, around-the-clock narcotic pain medication."[90]

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[88] Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).
[89] *See U.S. Food & Drug Admin., Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.*
[90] *Id.*

137. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "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 – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

138. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

139. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales

representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.[91]

140. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing;

[91] Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

3. The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

141. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this State and Plaintiff's Community. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

142. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[92] The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.[93] The same is true for veterans, who are more likely to use anti-anxiety

[92] 2016 CDC Guideline, *supra* note 55, at 13.
[93] *Id*. at 27.

drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

4. The Manufacturer Defendants Made Materially Deceptive Statements and Concealed Materials Facts

143. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

144. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites

Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids

to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

145. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic

non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

146. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-

cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

147. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing and speakers' bureau events.

148. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

5. The Manufacturer Defendants Fraudulently Concealed Their Misconduct

149. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants'

misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

150. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

151. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer

Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiff or Plaintiff's Community. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

C. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS

152. The Distributor Defendants owe a duty under both federal law (21 U.S.C. § 823, 21 CFR 1301.74) and Minnesota law (*e.g.,* Minn. Stat. §§ 152.11, 152.125, 256B.0638, and Minnesota Administrative Rules § 6800.1440), to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating

from Plaintiff's Community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

153. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

154. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

155. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in Minnesota and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

156. The opioid epidemic in Minnesota, including *inter alia* in Plaintiff's Community, remains an immediate ***hazard to public health and safety***.

157. The opioid epidemic in Plaintiff's Community is a temporary and continuous ***public nuisance*** and remains unabated.

158. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. The Distributor Defendants Have a Duty under Federal and State Law to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders

159. Opioids are a controlled substance and are categorized as "dangerous drugs" under Minnesota law. *See* Minn. Stat. § 152.02. These "Schedule II" drugs are controlled substances with a "high potential for abuse." 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

160. As wholesale drug distributors, each Distributor Defendant was required under Minnesota law to obtain a license as a wholesaler of controlled substances from the state board of pharmacy. Minnesota Administrative Rules § 6800.1400. Each Distributor Defendant is licensed by the Minnesota Board of Pharmacy and is a "registrant" or "licensee" as a wholesale distributor in the chain of distribution of Schedule II controlled substances and assumed a duty to comply with all security requirements imposed under the regulations adopted by the Minnesota Board of Pharmacy.

161. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. §0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Those requirements are adopted and incorporated into Minnesota law. Minnesota Administrative Rule § 6800.1440, subp. 11.

162. Each Distributor Defendant has an affirmative duty under federal and Minnesota law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must 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). Minnesota incorporates these requirements through Minnesota's Pharmacy Board Regulations, which mandate that "[w]holesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations." Minnesota Administrative Rule § 6800.1440, subp. 11.

163. The Minnesota Pharmacy Board requires that drug wholesalers "shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs." Minnesota Administrative Rule § 6800.1440, subp. 8.

164. Federal regulations, incorporated by Minnesota law (Minnesota Administrative Rule § 6800.1440, subp. 11), similarly impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

165. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a

normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

166. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.[94] Regardless, all flagged orders must be reported.[95]

167. These prescription drugs are regulated for the purpose of providing a "closed" system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[96]

[94] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017).
[95] *Id.*
[96] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

168. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[97]

169. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors 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."[98]

[97] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/about/mission/ (last visited Nov. 21, 2017).

[98] *See* Letter from Joseph T. , Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.).

170. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[99]

171. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, ***in addition*** to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[100] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[101] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[102]

172. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[103] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[104] The letter further explains:

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[99] *See* Brief for HDMA and NACDS, *supra* note 91, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").
[100] Rannazzisi Letter, *supra* note 92, at 2.
[101] *Id.* at 1.
[102] *Id.* at 2.
[103] *See* Rannazzisi Letter, *supra* note 92.
[104] *Id.*

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by

> registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[105]

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[106]

173. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[107]

174. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth

[105] *Id.*
[106] *Id.*
[107] *See* Brief of HDMA, *supra* note 20, 2012 WL 1637016, at *2.

recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[108]

175. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

176. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

177. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

178. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

179. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

[108] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, *filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

180. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

181. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Plaintiff's Community and the damages caused thereby.

2. The Distributor Defendants Breached their Duties

182. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[109]

183. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's Community, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[110]

[109] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

[110] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

184. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community, or which the Distributor Defendants knew were likely to be diverted to Plaintiff's Community, to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

185. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

186. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

187. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

188. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

189. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[111]

190. The federal and state laws at issue here are public safety laws.

191. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under Minnesota law.

192. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opiates.

193. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

194. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

[111] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

3. The Distributor Defendants Have Sought to Avoid and Have Misrepresented their Compliance with their Legal Duties

195. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

196. Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows**:**

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[112]

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[113]

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[114]

[112] Brief for HDMA and NACDS, *supra* note 93, 2016 WL 1321983, at *4–5.
[113] *Id.* at *8 (citations and quotation marks omitted).
[114] *Id.* at *14.

d. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[115]

e. The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose [] a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[116]

f. Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[117]

197. The positions taken by the trade groups are emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[118]

198. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id*. at 212. Master Pharmaceutical was in violation of legal requirements because it failed

[115] *Id.* at *22.
[116] *Id.* at *24-25.
[117] *Id.* at 26.
[118] *See* Brief of HDMA, *supra* note 20, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id*. at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id*. at 220.

199. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[119] Further, the 2017 Agreement specifically finds that McKesson "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)."[120] McKesson admitted that, during this time period, it "failed to

[119] *See* Administrative Memorandum of Agreement between the U.S. Dept. of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.
[120] *Id.* at 4.

maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers."[121]

200. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[122] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[123] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[124] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[125]

201. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate

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[121] *Id.*
[122] *Id.* at 4.
[123] *Id.*
[124] *Id.*; *see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download.
[125] *See* 2017 Settlement Agreement and Release, *supra* note 118, at 6.

those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

202. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[126] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[127] These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

[126] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[127] *Id.*

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order *to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an Order *to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

203. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[128]

204. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

205. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and

[128] *See* Lenny Bernstein & Scott Higham, *The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed- enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement- slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[129] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

206. Similarly, Defendant 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."[130] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

207. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

208. Meanwhile, the opioid epidemic rages unabated in the Nation, the State, and in Plaintiff's Community.

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[129] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

[130] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

209. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

210. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

211. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.

D. THE MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS

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

213. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

> maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or

> industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . . . .

21 USCA § 823(a)(1) (emphasis added).

214. Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958."). Like the Distributor Defendants, the Manufacture Defendants breached these duties.

215. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor

requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

216. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

217. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[131]

218. In the press release accompanying the settlement, the Department of Justice stated: "Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and

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

omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[132]

219. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[133]

220. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[134]

221. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in

[132] *Id.*
[133] *Id.*
[134] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

i. conduct adequate due diligence of its customers;

ii. detect and report to the DEA orders of unusual size and frequency;

iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[135]

222. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office

[135] *Id.*at 2-3.

of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[136]

223. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[137]

224. The same duties imposed by federal law on Mallinckrodt were imposed upon all Distributor Defendants.

225. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids

[136] *Id.* at 3-4.
[137] *Id.* at 5.

were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Distributor Defendants.

226. Through, *inter alia*, the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

227. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

228. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

229. The Manufacturer Defendants have misrepresented their compliance with federal law.

230. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

231. The Manufacturer Defendants' actions and omissions in failing to effective prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff's Community.

E. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND SUBSTANTIAL DAMAGES

232. As the Manufacturer Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid- related substance abuse, hospitalization, and death among the people of the State

and the Plaintiff's Community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like the Plaintiff's Community, fueling the epidemic.

233. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[138]

234. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[139]

235. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[140]

236. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.[141]

237. As shown above, the opioid epidemic has escalated in Plaintiff's Community with devastating effects. Substantial opiate-related substance abuse, hospitalization and death that mirror Defendants' increased distribution of opiates.

238. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of

[138] *See* Dart et al., *supra* note 11.
[139] *See* Volkow & McLellan, *supra* note 2.
[140] *See* Califf et al., *supra* note 3.
[141] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra* note 14.

opioids to Plaintiffs' Community and areas from which such opioids are being diverted into Plaintiff's Community, has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

239. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

240. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

241. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into the Plaintiff's Community.

242. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and Plaintiff's Community. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiff and Plaintiff's Community.

243. Defendants intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief, as alleged herein. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

244. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs association with past efforts to eliminate the hazards to public health and safety.

245. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

246. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[142]

247. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain. [143]

248. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."[144]

249. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff's Community.

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[142] *See* Rudd et al., *supra* note 19, at 1145.

[143] *See* Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

[144] *See* Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

F. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTED STATUTES OF LIMITATIONS AS DEFENSES

1. Continuing Conduct

251. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

252. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

2. Equitable Estoppel

253. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff, and Plaintiff's Community, that they are working to curb the opioid epidemic.

254. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and

efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[145]

255. Similarly, 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."[146]

256. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[147]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."

c. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

d. "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."

e. "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

[145] Bernstein et al., *supra* note 123.
[146] Higham et al., *supra* note 124.
[147] Brief for HDMA and NACDS, *supra* note 91, 2016 WL 1321983, at *3-4, *25.

Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

257. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database that will confirm their identities and the extent of their wrongful and illegal activities.

258. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, the State, and Plaintiff's Community were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's Community.

259. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

3. Fraudulent Concealment

260. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowingly and fraudulently concealing the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from the Plaintiff and Plaintiff's community. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its cause of action, as a result of Defendants' conduct.

261. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

262. In light of their statements to the media, in legal filings, and settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

263. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

V. LEGAL CAUSES OF ACTION

Count I:
Common Law Public Nuisance
(Against All Distributors)

264. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

265. Plaintiff alleges that Defendants wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

266. The Defendants have intentionally and/or unlawfully created an epidemic which is injurious to the health and safety of the members of the Band, is indecent and offensive to the senses, and interferes with the comfortable enjoyment of life and property.

267. Defendants intentionally, unlawfully, and recklessly manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing widespread distribution of prescription opioids in and/or to the Band and the Reservation, resulting in addiction and abuse, an elevated level of crime, death and injuries, a higher level of fear, discomfort and inconvenience, and direct costs to The Leech Lake Band of Ojibwe .

268. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted which has injured The Leech Lake Band of Ojibwe and its members.

269. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion.

Such conduct was illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

270. Defendants' knew or should have known that their conduct in distributing, selling, and marketing prescription opioids, or causing such opioids to be distributed and sold, would result in opioids being diverted and possessed and/or used illegally in Plaintiff's Community.

271. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

272. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff's Community will be diverted, leading to abuse, addiction, crime, and public health costs.

273. Because of the continued use and addiction caused by these illegally distributed opioids, the indecent and offensive opioid epidemic will continue to be injurious to the health and safety of the citizens of Plaintiff's Community, and interfere with the comfortable enjoyment of life and property therein.

274. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect.

275. Defendants know, or reasonably should know, that their conduct would be injurious to the health and safety of the members of the Band, is indecent and offensive to the senses, and interferes with the comfortable enjoyment of life and property.

276. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal and state law. *See*, e.g., 21 U.S.C. § 812 (b)(2); Minn. Stat. §152.02, subd. 3.

277. Defendants' conduct in marketing, distributing, and selling prescription opioids which the defendants know, or reasonably should know, will likely be diverted for non-legitimate, non-medical use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Plaintiff's Community and otherwise significantly and unreasonably interfere with the comfortable enjoyment of life and property.

278. It is, or should be, reasonably foreseeable to defendants that their conduct will cause deaths and injuries to residents in Plaintiff's Community, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

279. Defendants' conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

280. The presence of diverted prescription opioids in Plaintiff's Community, and the consequence of prescription opioids having been diverted in Plaintiff's

Community, proximately results in significant costs to the Band in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

281. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live.

282. Defendants' conduct is a direct and proximate cause of deaths and injuries to the Band, the Tribe and Plaintiff's Community.

283. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiff's Community, thereby interfering with the comfortable enjoyment of life and property.

284. The Band has sustained specific and special injuries because its damages include *inter alia* health services and law enforcement expenditures, as described in this Complaint.

285. Defendants knew, or should have known, that their conduct would naturally result in injuries and damages to the Band.

286. Nevertheless, Defendants continued such conduct in reckless disregard of or conscious indifference to those consequences.

287. As a direct and proximate result of the foregoing, the Band has been injured and suffered financial loss for which damages, injunctive, declaratory and other relief as may be available at law or equity is warranted.

Count II
Negligence and Negligent Misrepresentation
(Against All Defendants)

288. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

289. Plaintiff seeks economic damages which were the foreseeable result of Defendants' intentional and/or unlawful actions and omissions.

290. Each Defendant had an obligation to The Band to exercise reasonable and due care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs.

291. The harm to The Band was foreseeable, and in fact foreseen, by the Defendants.

292. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that its highly addictive product would be diverted and wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

293. Reasonably prudent manufacturers of pharmaceutical products would know that an aggressive marketing campaign designed to increase prescriptions of highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably

causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

294. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

295. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

296. As described throughout the complaint, in language expressly incorporated herein, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

297. As described throughout the Complaint, in language expressly incorporated herein, Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff's Community and destinations from which they knew opioids were likely to be diverted into Plaintiff's Community, in addition to other misrepresentations alleged and incorporated herein.

298. As described elsewhere in the Complaint in language expressly incorporated herein, Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

299. The Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and its lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

300. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

301. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

302. The causal connection between Defendants' breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

303. As described above in language expressly incorporated herein, Defendants' breaches of duty and misrepresentations caused and/or bear a causal connection with, and/or proximately resulted in, the damages sought herein.

304. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted away from medical, scientific, or industrial channels. However, Defendants breached their duties to monitor

for, report, and halt suspicious orders, breached their duties to prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

305. Defendants' unlawful and/or intentional actions create a rebuttable presumption of negligence under State law.

306. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' actions and omissions.

307. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, and compensatory, damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

Count III
Negligence Per Se
(Against AmerisourceBergin and McKesson)

308. Plaintiff re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

309. Defendant AmerisourceBergen operates a distribution center in Shakopee, Minnesota.

310. Defendant McKesson operates a distribution center in Maple Grove, Minnesota.

311. Minnesota Statutes § 151.01, *et seq*, and Minnesota Administrative Rules § 6800.1440, are public safety laws. AmerisourceBergin and McKesson each had a duty, under these laws and regulations, to maintain effective controls against theft and diversion of prescription opioids.

312. Defendants' actions and omissions in violation of the law constitute negligence per se.

313. It was foreseeable that the breach of duty described herein would result in the economic damages for which Plaintiff seeks recovery.

314. As described above in language expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

315. As described above in language expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, and proximately resulted in, harm and damages sought by the Plaintiff.

316. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence per se.

317. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, and compensatory damages, and all damages allowed by law to be paid by the Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest.

Count IV
Unjust Enrichment
(Against All Defendants)

318. Defendants have benefitted from the over prescription and use of opioids and the resulting opioid epidemic, which has required the Band to expend resources to combat. Accordingly, Defendants have been unjustly enriched at the expense of Plaintiff.

319. Defendants have received and retained unjust benefits at the expense of the Band and an inequity has resulted.

320. It is inequitable and unconscionable for Defendants to retain these benefits. Due to Defendants deceptive course of conduct in marketing and selling opioids, The Band was not aware of the true facts concerning the dangers opioids and their overuse posed to The Band.

321. Defendants knowingly accepted the unjust benefits of its fraudulent conduct and other misconduct.

322. As a result of Defendants' misconduct, the amount of its unjust enrichment should be disgorged and returned to The Band in an amount to be determined at trial.

Count V
Common Law Fraud
(Against All Defendants)

323. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

324. Defendants violated their general duty not to actively deceive, and have made knowingly false statements and have omitted and/or concealed information which

made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

325. As alleged herein, Defendants made false statements regarding their compliance with state and federal law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

326. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

327. As alleged herein, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading The Band, Plaintiff's community, the public, and persons on whom Plaintiff relied.

328. These false representations and concealments were reasonably calculated to deceive The Band, Plaintiff's community, and the physicians who prescribed opioids for persons in Plaintiff's Community, were made with the intent to deceive, and did in fact deceive these persons, The Band, and Plaintiff's Community.

329. The Band, Plaintiff's Community, and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

330. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. Plaintiff's injuries were proximately caused by this reliance.

331. The injuries alleged by Plaintiff herein were sustained as a direct and proximate cause of Defendants' fraudulent conduct.

332. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment.

333. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest.

Count VI
Unlawful Trade Practices Minn. Stat. § 325D.09, et seq,
(Against All Defendants)

334. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

335. Minnesota Statutes §§325D.09, *et seq*, read in pertinent part:

> 325D.13 QUALITY, MISREPRESENTED
> No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise.

336. Defendants are persons for purposes of this statute.

337. As alleged herein, Defendants have misrepresented the addictive quality of opioids. The Manufacturer Defendants engaged in an aggressive marketing campaign, which in part sought to downplay the dangerousness of these drugs, while promoting them for chronic pain for which they knew the drug were not safe or suitable.

338. Because of the dangerously addictive nature of these drugs, the Defendants' manufacturing, marketing, sales, and/or distribution practices unlawfully caused an opioid and heroin epidemic in the State and Plaintiff's Community.

339. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

340. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

341. The Manufacturer Defendants also used exaggeration and/or created ambiguity as to material facts and omitted material facts, which tended to deceive and/or did in fact deceive.

342. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of State law.

343. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted

or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

344. The Band has been damaged by Defendants' violation of this statute. Because of Defendants' omissions and misrepresentations to The Band, its residents, and their medical professionals, The Band has incurred significant costs in order to, *inter alia*, enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

345. Plaintiff seeks injunctive relief and actual damages under Minn. Stat. § 325D.15, as well as under Minn. Stat. §8.31, which creates a private right of action when the action would benefit the public. The present action benefits the public, both in Plaintiff's Community, as well as all of Minnesota, by stemming the flow of diverted opioid drugs into the state, and providing The Band the necessary resources, both monetary and non-monetary, to redress the opioid epidemic and treat its victims. Stemming the flow of illegally distributed prescription opioids, and slowing the flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live.

Count VII
Uniform Deceptive Trade Practices Act Minn. Stat. § 325D.43, et seq.
(Against All Defendants)

346. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

347. Minnesota Statutes § 325D.43, *et seq.*, read in pertinent part:

325D.44 DECEPTIVE TRADE PRACTICES

> A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person:
>
> (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
>
> (7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
>
> (13) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

348. Defendants' unfair, deceptive, and unconscionable representations, concealments, and omissions were reasonably calculated to create confusion and misunderstanding as to the nature and efficacy of opioid drugs, and in doing so deceive the State, the public, and The Band.

349. As alleged herein, Defendants have misrepresented the addictive quality of opioids. The Manufacturer Defendants engaged in an aggressive marketing campaign, which in part sought to downplay the dangerousness of these drugs, while promoting them for chronic pain for which they knew the drug were not safe or suitable.

350. Because of the dangerously addictive nature of these drugs, the Defendants' manufacturing, marketing, sales, and/or distribution practices unlawfully caused an opioid and heroin plague and epidemic in the State and Plaintiff's Community.

351. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

352. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

353. The Manufacturer Defendants also used exaggeration and/or created ambiguity as to material facts and omitted material facts, which tended to deceive and/or did in fact deceive.

354. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of State law.

355. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

356. As a result of Defendants' omissions and misrepresentations regarding the use and characteristics of opioids to The Band, its residents, and their medical professionals, The Band has incurred significant harms including law enforcement costs, medical costs relating to opioid abuse and addiction, and other social and medical costs.

357. Plaintiff seeks injunctive relief as well as costs and fees incurred in pursuing this claim, pursuant to MINN. STAT. §325D.45.

Count VIII
False Statement in Advertisement Minn. Stat. § 325F.67
(Against All Defendants)

358. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

359. Minn. Stat. § 325F.67 reads in pertinent part:

> Any person, firm, corporation, or association who, with intent to sell . . . or with intent to increase the consumption thereof, . . . makes, publishes, disseminates, circulates, or places before the public . . . an advertisement of any sort regarding merchandise . . . for use, consumption, purchase, or sale, which advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall, whether or not pecuniary or other specific damage to any person occurs as a direct result thereof, be guilty of a misdemeanor, and any such act is declared to be a public nuisance and may be enjoined as such.

360. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign designed to promote the belief that opioid drugs could safely be used in a non-addictive manner.

361. By way of example, Actavis's predecessor created a patient brochure for Kadian in 2007 that deceptively stated that needing to up one's dose to achieve the same treatment outcome was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

362. Cephalon and Purdue sponsored research and publications that falsely and deceptively stated opioids did not have "ceiling dose."

363. Purdue created websites, available to the public that instructed patients to seek new medical providers out if their current provider would not increase their dose.

364. Defendants' false and deceptive advertising practices resulted in increased opioid dosages being prescribed to the Band residents, increasing the incidence of opioid addiction and overdose in Plaintiff's Community.

365. Because of Defendants' false and deceptive advertising practices to the Band, its residents, and their medical professionals, the Band has incurred significant costs in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

366. Plaintiffs seek injunctive relief and actual damages under Minn. Stat. § 8.31, which creates a private right of action when the action would benefit the public. The present action benefits the public, both in Plaintiff's Community, as well as all of Minnesota, by stemming the flow of diverted opioid drugs into the state, and providing the Band the necessary resources, both monetary and non-monetary, to redress the opioid epidemic and treat its victims. Stemming the flow of illegally distributed prescription opioids, and slowing the flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make the Band a safer place to live.

Count IX
Minnesota Prevention of Consumer Fraud Act Minn. Stat. § 325F.68 et seq.
(Against All Defendants)

367. Minnesota Statutes §§325D.13, 325D.44 and 325F.69, prohibit misrepresenting the quality of goods as well as sales sounding in fraud, misrepresentation, or deceptive practices, providing in pertinent part:

> 325F.69 UNLAWFUL PRACTICES
> Subdivision 1. Fraud, misrepresentation, deceptive practices. The act, use, or employment by any person of any fraud, false pretense, false

> promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoinable as provided in section 325F.70.

368. Defendants committed repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in connection with the sale of merchandise.

369. Defendants' unfair, deceptive, and unconscionable representations, concealments, and omissions were reasonably calculated to deceive the State, the public, and the Band.

370. As described more specifically above, Defendants' representations, concealments, and omissions constitute a willful course of conduct which continues to this day.

371. Each Defendant failed to report and/or prevent the diversion of highly addictive prescription drugs to illegal sources.

372. Each Defendant failed to report and/or prevent the diversion of highly addictive prescription drugs. Because of the dangerously addictive nature of these drugs, the Distributor Defendants' manufacturing, marketing, sales, and distribution practices unlawfully caused an opioid and heroin plague and epidemic. Each Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

373. The Defendants also omitted material facts, causing confusion or misunderstanding as to approval or certification of goods or services.

374. The Defendants failed to disclose the material facts that *inter alia* they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

375. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

376. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

377. The Manufacturer Defendants also used exaggeration and/or ambiguity as to material facts and omitted material facts, which had a tendency to deceive and/or did in fact deceive.

378. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of State law.

379. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions

about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

380. The damages which Plaintiff seeks to recover were sustained as a direct and proximate cause of the Manufacturer and Distributor Defendants' intentional and/or unlawful actions and omissions. Because of Defendants' omissions and deceptive misrepresentations to the Band, its residents, and their medical professionals, the Band has incurred significant costs in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

381. Plaintiff seeks injunctive relief and actual damages under Minn. Stat. § 8.31, which creates a private right of action when the action would benefit the public. The present action benefits the public, both in Plaintiff's Community, as well as all of Minnesota, by stemming the flow of diverted opioid drugs into the state, and providing The Band the necessary resources, both monetary and non-monetary, redress the opioid epidemic and treat its victims. Stemming the flow of illegally distributed prescription opioids, and slowing the flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make the Band a safer place to live.

Count X
Lanham Act 15 U.S.C. §1125(a)(l)(B)
(Against All Defendants)

382. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

383. The Lanham Act, 15 U.S.C. § 1125(a), provides in pertinent part:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which-
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

384. As alleged herein, and incorporated into this count, the Defendants committed repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in connection with the sale of goods and service.

385. As alleged herein, and incorporated into this count, the Defendants engaged systematic false and misleading advertising campaign, via print advertising, promotional materials and other items designed to reach consumers.

386. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, and compensatory, damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

RELIEF

WHEREFORE, Plaintiff respectfully requests:

A. Judgment temporarily and permanently enjoining the Defendants, and all associated entities, employees, and/or agents from engaging in further acts in violation of Minnesota's Unlawful Trade Practices Act, Uniform Deceptive Trade

Practices Act, False Statement in Advertisement Act, and Prevention of Consumer Fraud Act, as well as, acts prohibited under the Lanham Act, as alleged in this complaint;

B. Judgment declaring that Defendants have created a public nuisance, and an order for Defendants to compensate Plaintiff for past harm and abatement of the nuisance;

C. Judgment in favor of Plaintiff awarding any and all applicable statutory and civil penalties;

D. An order requiring Defendants to pay both pre- and post-judgment interest on any amounts awarded;

E. An award of costs and attorneys' fees, as allowed by law; and

F. Such other or further relief as the Court may deem appropriate, just, and equitable.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff requests a jury trial on all matters so triable.

Dated: December 19, 2017

LOCKRIDGE GRINDAL NAUEN P.L.L.P.

By: s/ Yvonne M. Flaherty
Yvonne M. Flaherty (#267600)

Richard A. Lockridge (#0064117)
David W. Asp (#344850)
100 Washington Avenue South, Suite 2200
Minneapolis, MN 55401
Telephone: (612) 339-6900
ymflaherty@locklaw.com
ralockridge@locklaw.com
dwasp@locklaw.com

Daniel E. Gustafson (#0202241)
Amanda M. Williams (#0341691)
David A. Goodwin (#0386715)
Eric S. Taubel (#0392491)
GUSTAFSON GLUEK PLLC
Canadian Pacific Plaza - Suite 2600
120 South 6th Street
Minneapolis, MN 55402
Telephone: (612) 333-8844
dgustafson@gustafsongluek.com
awilliams@gustafsongluek.com
dgoodwin@gustafsongluek.com
etaubel@gustafsongluek.com

Counsel for Plaintiff