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Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
DISTRICT OF WYOMING

NORTHERN ARAPAHO TRIBE	:	**Case No.:** 18-CV-57-J
	:	
Plaintiff,	:	**Judge:**
	:	
v.	:	
	:	
PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., ENDO	:	**COMPLAINT AND JURY DEMAND**

HEALTH SOLUTIONS INC., ENDO	:
PHARMACEUTICALS INC.,	:
ALLERGAN PLC, ALLERGAN SALES	:
LLC, ALLERGAN USA, INC.,	:
WATSON PHARMACEUTICALS, INC.,	:
WATSON LABORATORIES, INC.,	:
ACTAVIS ELIZABETH LLC,	:
MALLINCKRODT PLC,	:
MALLINCKRODT LLC, MCKESSON	:
CORP., CARDINAL HEALTH, INC.,	:
AND AMERISOURCEBERGEN CORP.,	:
	:
Defendants.	:

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COMPLAINT

Plaintiff, the Northern Arapaho Tribe, by and through its undersigned counsel, and for its Complaint against Defendants, alleges as follows:

I. INTRODUCTION

1. An epidemic of prescription opioid abuse is devastating the United States. Indian Country has been particularly hard hit, causing Plaintiff Northern Arapaho Tribe to suffer substantial loss of resources, economic damages, and damages to the health and welfare of its members.

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.[1] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[2]

3. This epidemic has been building for years. The conditions for its creation and acceleration were intentionally brought about by Defendants, who made billions of dollars off the epidemic.

4. The effects of the opioid crisis have been exacerbated by Defendants' efforts to conceal or minimize the risks of—and to circumvent or ignore safeguards against—opioid abuse.

5. The Tribe has seen child welfare and foster care costs associated with opioid-addicted parents skyrocket, their health services have been overwhelmed, education and addiction therapy costs have substantially increased, and almost every tribal member has been affected.

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[1] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

[2] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

6. These costs could have been—and should have been—prevented by the opioid industry. The prescription drug industry is required by statute and regulation to secure and monitor opioids at every step of the stream of commerce, thereby protecting opioids from theft, misuse, and diversion. The industry is also supposed to implement processes to alert it to "red flags" that stop suspicious or unusual orders by pharmacies, doctors, clinics, or patients.

7. Instead of acting with reasonable care and in compliance with their legal duties, the Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the process.

8. Defendants also flooded the market with false statements designed to persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those claims were false.[3]

9. Defendants' actions directly and foreseeably caused damages to the Tribe, including the costs of (a) medical and therapeutic care, prescription drug purchases, and other treatment costs for patients suffering from opioid addiction or disease, overdose, or death; (b) counseling, treatment, and rehabilitation services; (c) treatment of infants born with opioid-related medical conditions; (d) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation; and (e) law enforcement and public safety relating to the opioid epidemic within the tribal communities. The Tribe has also suffered substantial damages due to the lost productivity of tribal members, increased administrative costs, and the lost opportunity for growth and self-determination. These damages have been suffered and continue to be suffered directly, by the Tribe.

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[3] *See* Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org/ (last accessed March 15, 2018).

10. The Tribe also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

11. Plaintiff brings this civil action against Defendants in order to abate and remedy the opioid public health epidemic in the Northern Arapaho Tribe caused by Defendants. As a result of Defendants' wrongful conduct including, but not limited to, deceptively marketing and distributing prescription opioid drugs throughout the country, the State of Wyoming, and in particular throughout the Northern Arapaho Tribe Community, Plaintiff has incurred significant damages, and continues to suffer harm and incur damages for which this civil action seeks remedy. The Tribe brings this action in its own capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of all members of the Tribe.

12. Plaintiff alleges damages from each Defendant in excess of $75,000.00, exclusive of interest and costs.

II. PARTIES

A. Plaintiff.

13. The Northern Arapaho Tribe is a federally recognized sovereign Indian nation, with its seat of government in Ethete, Wyoming. The Northern Arapaho Tribe exercises inherent governmental authority on behalf of the Tribe itself and its members. The Northern Arapaho Tribe is located on the Wind River Indian Reservation, occupying land in Fremont and Hot Springs counties, Wyoming.

14. The Tribe has inherent sovereignty over unlawful conduct that takes place on, or has a direct impact on, land that constitutes Indian Country within the Tribe's jurisdiction. Federal law recognizes the Tribe's authority over its members and its territory, specifically the authority to promote the autonomy and the health and welfare of the Tribe. Defendants engaged in activities and conduct that takes place on or have a direct impact on the Tribe, its lands, and its

territory. The distribution and diversion of opioids into Wyoming and into the Tribe's territory and surrounding areas, created the foreseeable opioid crisis and opioid public nuisance for which the Tribe seeks relief.

15. The Tribe has standing to recover damages incurred as a result of Defendants' actions and omissions under applicable statutory and common law, including RICO (18 U.S.C. 1961, *et seq.*)

16. Members of the Tribe affected by the opioid crisis described in this complaint live on the Tribe's reservation, as well as throughout Wyoming.

B. Pharmaceutical Defendants.

17. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. Upon information and belief no partners of Purdue Pharma L.P. are citizens of Wyoming. 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 The Purdue Frederick Company are referred to collectively as "Purdue").

18. 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. Cephalon, Inc. is a Delaware corporation with its principal place of business in Pennsylvania. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation with its principal place of business in Pennsylvania. Both Cephalon, Inc. and Teva Pharmaceutical USA, Inc. are subsidiaries of Teva Pharmaceutical Industries Ltd.

(Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as "Cephalon").

19. ALLERGAN PLC (f/k/a Actavis PLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. In 2012, Watson Pharmaceuticals Inc. acquired Actavis Inc. and the combined company took on the name Actavis Inc. After the purchase of Warner Chilcott PLC in 2013, Actavis Inc. became Actavis PLC. In 2015, after acquiring Allergan Inc., Actavis PLC ultimately changed its name to Allergan PLC.

20. ALLERGAN SALES LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business in New Jersey. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in California. Upon information and belief each of these defendants is owned by Allergan PLC which uses them to market and sell its drugs in the United States.

21. WATSON LABORATORIES INC. and ACTAVIS ELIZABETH LLC were previously subsidiaries of Allergan PLC, however, through information and belief, these companies are now owned by Teva Ltd. due to Teva Ltd.'s purchase of Allergan PLC's generic division in 2016. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in California. Actavis Elizabeth LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business in New Jersey. (Allergan PLC, Allergan Sales LLC, Allergan USA, Inc., Watson Laboratories Inc., Actavis Elizabeth LLC, Teva Ltd., and Teva USA are referred to collectively as "Allergan").

22. 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. 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. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to collectively as "Janssen"). Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical's products and corresponds with the FDA regarding Janssen's products.

23. 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 collectively as "Endo").

24. 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. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC. Upon information and belief no members of Mallinckrodt, LLC are citizens of Wyoming. Mallinckrodt, PLC and Mallinckrodt, LLC are collectively referred to as "Mallinckrodt."

25. Collectively, Purdue, Cephalon, Janssen, Endo, Allergan, and Mallinckrodt are the "Pharmaceutical Defendants."

C. Distributor Defendants.

26. CARDINAL HEALTH, INC. ("Cardinal") is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio.

27. AMERISOURCEBERGEN CORPORATION ("AmerisourceBergen") is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania.

28. MCKESSON CORPORATION ("McKesson") is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

29. Collectively, Cardinal, AmerisourceBergen, and McKesson are the "Distributor Defendants."

III. JURISDICTION AND VENUE

30. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332, as on information and belief, complete diversity exists between Plaintiff and Defendants, and the amount in controversy exceeds $75,000.00 for each Defendant.

31. This Court also has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action presents a federal question.

32. This Court also has subject matter jurisdiction under 28 U.S.C. § 1362 because this action involves claims brought by a recognized Indian tribe wherein the matter in controversy arises under the laws of the United States.

33. This Court has personal jurisdiction over all Defendants because all Defendants have substantial contacts and business relationships with the State of Wyoming, including, consenting to be sued in Wyoming by registering an agent for service of process, and/or obtaining a distributor license, and/or have purposefully availed themselves of business

opportunities within the State of Wyoming, including by marketing, distributing, or selling prescription opioids within the State of Wyoming and within the Tribe's community.

34. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contact. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998).

35. Venue is proper in this Court under 28 U.S.C. § 1391(b) and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to this action occurred in this judicial district and because all defendants are subject to this Court's exercise of personal jurisdiction.

IV. ADDITIONAL FACTUAL ALLEGATIONS

A. Defendants' Business Activities Overview.

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

37. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S., including Wyoming. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual 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). Purdue has registered with the Wyoming State Board of Pharmacy to do business in Wyoming.

38. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the U.S., including in Wyoming. The FDA approved Actiq and Fentora only for the management of breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

39. 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 marketed and sold in Wyoming, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly owned subsidiary of Teva Ltd. on prescription savings cards distributed in Wyoming, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. 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." Through interrelated operations like these, Teva Ltd. operates in Wyoming and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the 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 Pharmaceuticals USA Inc. has registered with the Wyoming State Board of Pharmacy to do business in Wyoming. (Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as "Cephalon.")

40. Janssen manufactures, promotes, sells, and distributes drugs in the U.S., including in Wyoming, including the opioid Duragesic (fentanyl). Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

41. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S., including in Wyoming. 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 U.S., including in Wyoming, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo has registered with the Wyoming State Board of Pharmacy to do business in Wyoming.

42. Allergan 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 U.S., including in Wyoming. Allergan has registered businesses with the Wyoming State Board of Pharmacy to do business in Wyoming.

43. 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. Mallinckrodt has registered with the Wyoming State Board of Pharmacy to do business in Wyoming.

44. Cardinal distributes prescription opioids to providers and retailers, including in Wyoming. Cardinal is registered to do business and receive service of process in Wyoming. Cardinal is also registered with the Wyoming State Board of Pharmacy as a wholesale prescription drug distributor in Wyoming.

45. AmerisourceBergen distributes prescription opioids to providers and retailers, including in Wyoming. AmerisourceBergen is registered to do business and receive service of process in Wyoming. AmerisourceBergen is also registered with the Wyoming State Board of Pharmacy as a wholesale prescription drug distributor in Wyoming.

46. McKesson distributes prescription opioids to providers and retailers, including in Wyoming. McKesson is registered to do business and receive service of process in Wyoming. McKesson is also registered with the Wyoming State Board of Pharmacy as a wholesale prescription drug distributor in Wyoming.

47. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will voluntarily disclose the data necessary to identify with specificity the transactions that will form the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

48. Collectively, AmerisourceBergen, Cardinal, and McKesson 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, McKesson, and AmerisourceBergen predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. The Tribe has reason to believe each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into the Tribe's communities. The Tribe names each of the "Big 3" herein as defendants and places the industry on notice that the Tribe is acting to abate the public nuisance plaguing their communities. The Tribe 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.

B. Overview of the Opioid Epidemic.

49. The term "opioid" includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These

medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."[4]

50. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

51. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain, like back pain, migraines, and arthritis. According to Dr. Caleb Alexander, director of Johns Hopkins University's Center for Drug Safety and Effectiveness, "[opioids] have very, very high inherent risks . . . and there's no such thing as a fully safe opioid."[5]

52. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly over time no longer responds to the drug as strongly as before, thus requiring a higher dose to achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

53. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used 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

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[4] *See* U.S. FDA, Opioid Medications, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm (last accessed March 12, 2018).

[5] Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public Integrity, available at https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution (last accessed March 12, 2018).

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.

54. To take advantage of the much larger and more lucrative market for chronic pain patients, the Pharmaceutical Defendants had to change this.[6]

55. As described herein, Defendants engaged in conduct that directly caused doctors to unwittingly prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their obligations to prevent diversion of the highly addictive substance.

56. As a result of Defendants' wrongful conduct, the number of prescriptions for opioids increased sharply, reaching nearly 250,000,000 prescriptions in 2013, almost enough for every person in the United States to have a bottle of pills. In 2016, the national average for dispensed prescriptions for opioids was 66.5 per 100 persons. Wyoming averaged 71.1 per 100 persons. Wyoming's Fremont County and Hot Springs County, where members of the Tribe reside, had two of the highest prescription rates of 83.3 per 100 and 98.1 per 100, respectively. Many Americans, including Wyoming Residents and members of the Tribe, are now addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United States, an increase of more than 22 percent over the previous year. The New York Times reported in September 2017 that the opioid epidemic is now killing babies and toddlers because ubiquitous, deadly opioids are "everywhere" and are mistaken as candy.[7] The opioid epidemic has been declared a public health emergency by the President of the United States.

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[6] *See* Harriet Ryan et al., *`You want a description of hell?' OxyContin's 12-hour problem*, L.A. Times, May 5, 2016, available at http://www.latimes.com/projects/oxycontin-part1/ (last accessed March 12, 2018).

[7] Julie Turkewitz, *"The Pills are Everywhere:" How the Opioid Crisis Claims Its Youngest Victims*, N.Y. Times, available at https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html (last accessed March 15, 2018).

57. The wave of addiction was created by the increase in opioid prescriptions. One in four Americans receiving long-term opioid therapy struggles with opioid addiction. Nearly two million Americans have a prescription opioid use disorder.

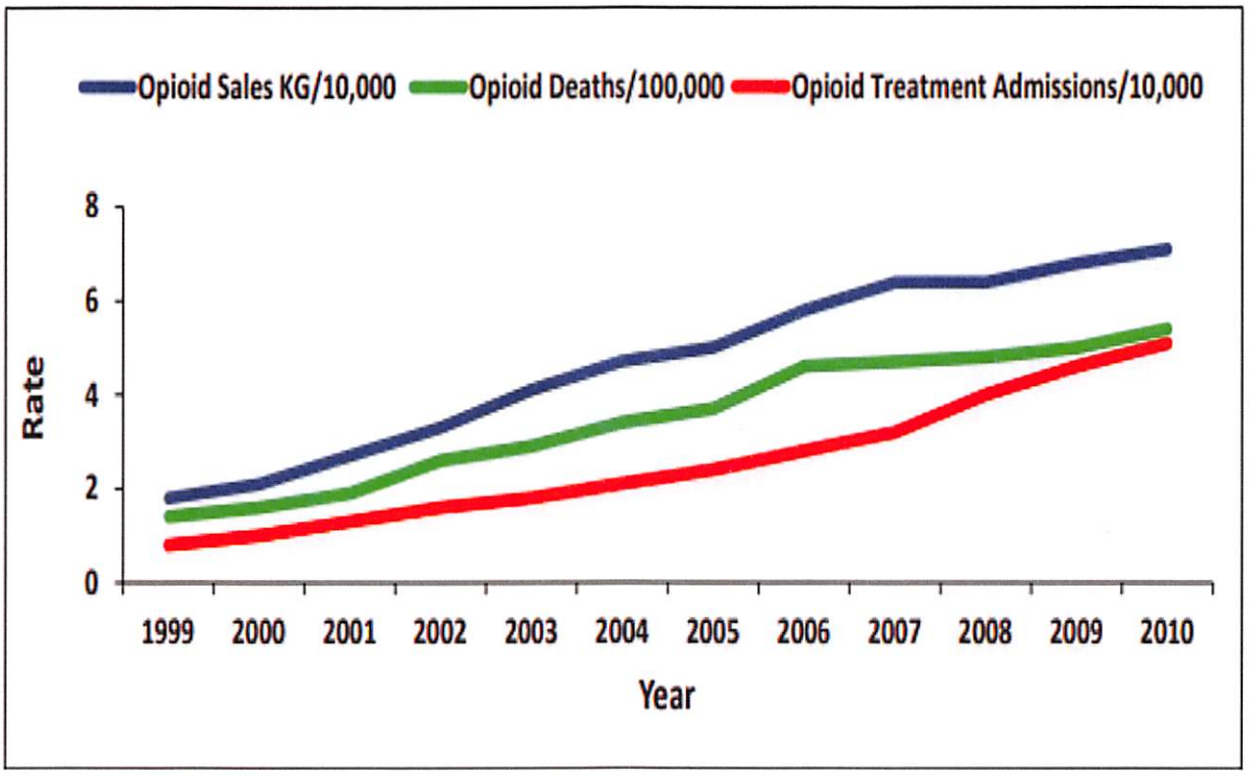
58. According to the NIH's National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed opioids for chronic pain misuse them. Between eight and ten percent develop an opioid use disorder. Four to six percent of people who misuse prescription opioids transition to heroin abuse, and about 80 percent of people who use heroin first misused prescription opioids.

59. Deaths from prescription opioids have quadrupled in the past 20 years.

60. Treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have also dramatically increased.

61. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC[8], opioid deaths and treatment admissions are tied to opioid sales:

[8] U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed March 15, 2018).



62. People who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. Heroin is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years.

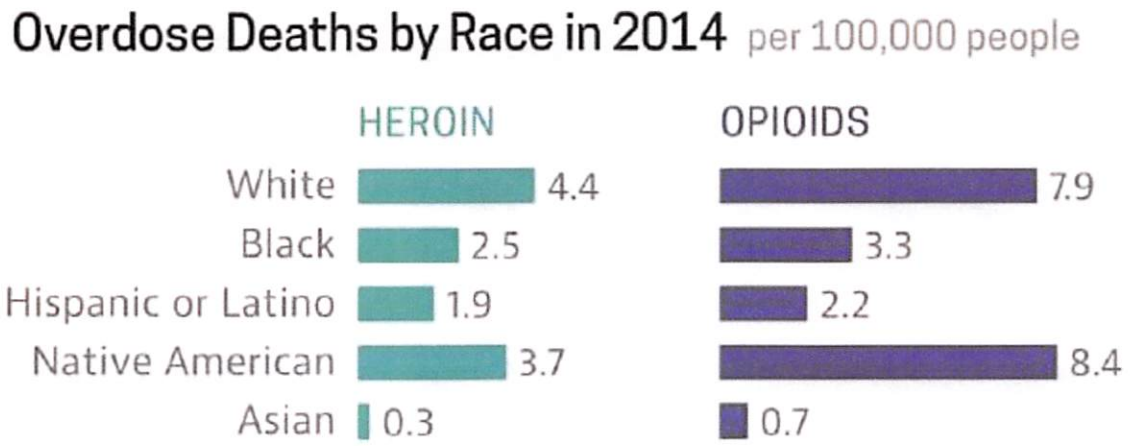
63. Prescription opioid abuse "is a serious national crisis that affects public health as well as social and economic welfare." The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[9]

64. Prescription opioid abuse disproportionately impacts American Indian communities, including the Tribe. The CDC reported in 2012 that one in ten American

[9] Opioid Crisis, NIH, National Institute on Drug Abuse, available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis (last visited March 30, 2018).

Indians/Native Americans (over the age of 12) used prescription pain medicine for nonprescription purposes, compared with 1 in 20 whites and 1 in 30 African-Americans.[10] The Plaintiff Tribe is also disproportionately affected.

65. Drug overdose deaths among all Americans increased more than 200 percent between 1999 and 2015. In that same time, the death rate rose by more than 500 percent among Native Americans and native Alaskans:[11]



66. The death rate for heroin overdoses among Native Americans has also skyrocketed, rising 236 percent from 2010 to 2014.[12]

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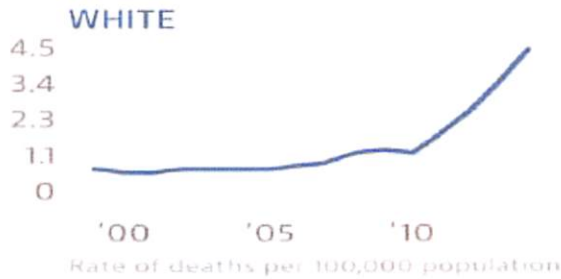
[10] US Medicine (2012). IHS Grapples with Pervasive Prescription Opioid Misuse in Tribal Areas. Addiction. Available at http://www.usmedicine.com/clinical-topics/addiction/ihs-grapples-with-pervasive-prescription-opioid-misuse-in-tribal-areas/ (last visited March 15, 2018).

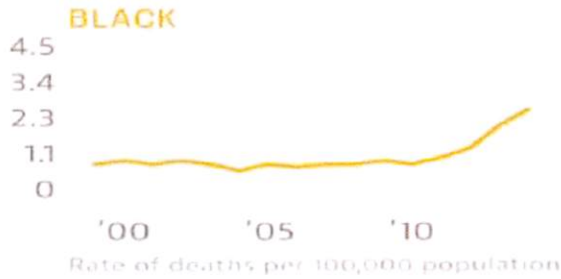
[11] Eugene Scott, *Native Americans, among the most harmed by the opioid epidemic, are often left out of the conversation*, Washington Post (Oct. 30, 2017), available at https://www.washingtonpost.com/news/the-fix/wp/2017/10/30/native-americans-among-the-most-harmed-by-the-opioid-epidemic-are-often-left-out-of-conversation (last accessed March 15, 2018).

[12] Dan Nolan and Chris Amico, *How Bad is the Opioid Epidemic?*, PBS.org (Feb. 23, 2016), available at https://www.pbs.org/wgbh/frontline/article/how-bad-is-the-opioid-epidemic/ (last accessed March 15, 2018).

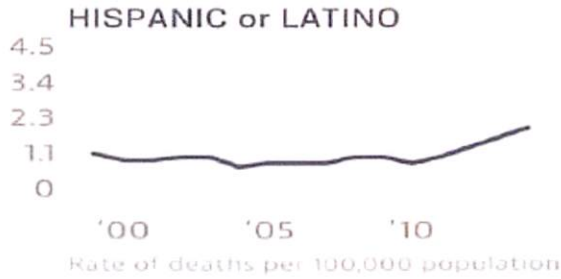
Rate of Deaths from Heroin Overdoses, by Race



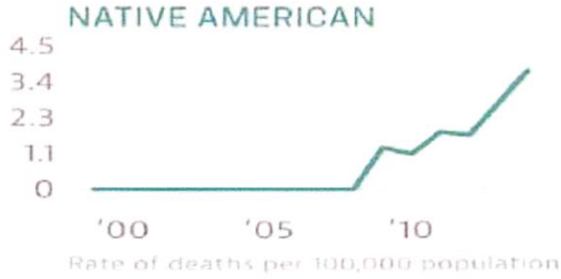
267%
increase from 2010–2014



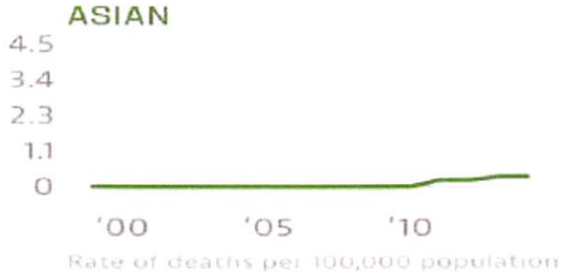
213%
increase from 2010–2014



137%
increase from 2010–2014



236%
increase from 2010–2014



Figures are too small to reliably calculate percentage increase.

C. The Science Behind Pain Medicine.

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

67. The practice of medicine hinges on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as the risk of non-treatment. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risks of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

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

69. The FDA-approved drug labels on Defendants' opioid drugs do not attempt to advise physicians how to maximize the benefit and minimize the risk for patients on long-term chronic opioid therapy. The labels contain no dosing cap above which it would be unsafe for any doctor to prescribe to any patient. Nor do any of the labels provide a duration limit, after which the risks to a patient might increase. Thus, doctors and patients rely more heavily on educational materials, such as treatment guidelines, CMEs, scientific and patient education articles and websites, to inform their treatment decisions.

2. The Use of Opioids Is Associated with Known and Substantial Risks.

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

71. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain—particularly on the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States. Many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

72. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of excessive dose.

73. Most patients with more than a few weeks of opioid therapy will experience withdrawal symptoms if opioids are discontinued (commonly referred to as "dependence"). Once dependent, a patient experiences deeply unpleasant symptoms when his or her current dose of opioids loses effect and is not promptly replaced with a new dose. Among the symptoms reported in connection with opioid withdrawal are: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long opioids were used.

74. When under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction he or she has

become accustomed to. At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. The FDA has acknowledged that available data suggest a relationship between increased dose and risk of adverse effects.

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

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

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

78. Each of these risks and adverse effects—dependence, tolerance, and addiction—is disclosed in the labels for Defendants' opioids (though, as described below, not in Defendants' marketing). Prior to Defendants' deceptive marketing scheme, each of these risks was well-recognized by doctors and seen as a reason to use opioids to treat chronic pain sparingly and only after other treatments had failed.

79. Opioids vary by duration. Long-acting opioids are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Some opioids may be taken in short-acting formulations, which last for approximately 4-6 hours. Short-acting opioids may be taken in addition to long-acting opioids to address "episodic pain." Defendants promoted the idea that pain should be treated first by taking long-acting opioids continuously and then by taking short-acting, rapid onset opioids on top of that.

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

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

82. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.

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

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

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

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

86. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo-controlled studies appeared in the 1990s, and revealed evidence only for short-term efficacy and only in a minority of the patients in the study.

87. Subsequent reviews of the use of opioids consistently note the lack of data to assess long-term outcomes. On the contrary, evidence exists to show that opioid drugs are not effective to treat chronic pain, and may worsen patients' health.

D. The Pharmaceutical Defendants Spread False or Misleading Information about the Safety of Opioids.

88. Each Pharmaceutical Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used for

treatment of chronic pain, resulting in opioid treatment for a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Pharmaceutical Defendant spent, and continued to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

89. The deceptive marketing schemes included, among others, (1) false or misleading direct, branded advertisements; (2) false or misleading direct-to-physician marketing, also known as "detailing"; (3) false or misleading materials speaker programs, webinars, and brochures; and (4) false or misleading unbranded advertisements or statements by purportedly neutral third parties that were really designed and distributed by the Pharmaceutical Defendants. In addition to using third parties to disguise the source of their misinformation campaign, the Pharmaceutical Defendants also retained the services of certain physicians, known as "key opinion leaders" or "KOLs" to convince both doctors and patients that opioids were safe for the treatment of chronic pain.

90. The Pharmaceutical 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 seriousness 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 dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Pharmaceutical 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 Pharmaceutical Defendants' claims.

91. The Pharmaceutical 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, through unbranded marketing and through industry-funded front groups.

92. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that same evidence.

93. The Pharmaceutical Defendants began their marketing schemes decades ago and continue them today.

94. As discussed herein, the 2016 CDC Guideline makes it patently clear that their schemes were and continue to be deceptive.

95. On information and belief, as a part of their deceptive marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including in Wyoming.

96. For example, on information and belief, the Pharmaceutical 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 schooled in treating pain and the risks and benefits of opioids and therefore more likely to accept the Pharmaceutical Defendants' misrepresentations.

97. On information and belief, the Pharmaceutical Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain.

98. The Pharmaceutical 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 observed that existing evidence showed that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concluded that there are special risks of long-term opioid use for elderly patients and recommended that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for posttraumatic stress disorder, which interact dangerously with opioids.

99. To increase the impact of their deceptive marketing schemes, on information and belief the Pharmaceutical Defendants coordinated and created unified marketing plans to ensure that the Pharmaceutical Defendants' messages were consistent and effective across all their marketing efforts.

100. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $1.1 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[13] 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 the heavy marketing of opioids to

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[13] *See* Katherine Eban, *OxyContin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011; David Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times, August 10, 2016.

doctors, many of whom "were even taught — incorrectly — that opioids are not addictive when prescribed for legitimate pain."[14]

101. The Pharmaceutical 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 Pharmaceutical Defendants Engaged in False and Misleading Direct Marketing of Opioids.

102. The Pharmaceutical Defendants' direct marketing of opioids generally proceeded on two tracks: advertising campaigns and direct-to-physician marketing.

103. First, each Pharmaceutical Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Pharmaceutical Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

104. A number of the Pharmaceutical Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example:

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

b. On 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.

105. Although Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, they continued to disseminate them elsewhere.

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[14] Murthy, *supra* note 3.

106. The direct advertising disseminated by the Pharmaceutical Defendants did not disclose studies that were not favorable to their products, nor did they disclose that they did not have clinical evidence to support many of their claims.

2. The Pharmaceutical Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information about Opioids.

107. Second, each Pharmaceutical Defendant promoted the use of opioids for chronic pain through "detailers" — sophisticated and specially trained sales representatives who visited individual doctors and medical staff in their offices — and small group speaker programs.

108. The Pharmaceutical Defendants invested heavily in promoting the use of opioids for chronic pain through detailers and small group speaker programs.

109. The Pharmaceutical Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, the Pharmaceutical Defendants spend in excess of $168 million in 2014 alone on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

110. On information and belief, these detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, including doctors in Wyoming. For example, on information and belief, the Pharmaceutical Defendants' detailers, over the past two years, continue to falsely and misleadingly:

a. Describe the risk of addiction as low or fail to disclose the risk of addiction;

b. Describe their opioid products as "steady state" — falsely implying that these products are less likely to produce the highs and lows that fuel addiction — or as less likely to be abused or result in addiction;

c. Tout the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction;

d. State that there is no maximum dose and that doctors can safely increase doses without disclosing the significant risks to patients at higher doses;

e. Discuss "pseudoaddiction";

f. State that patients would not experience withdrawal if they stopped using their opioid products;

g. State that their opioid products are effective for chronic pain without disclosing the lack of evidence for the effectiveness for chronic pain without disclosing the lack of evidence for the effectiveness of long-term opioid use; and

h. State that abuse-deterrent formulations are tamper or crush resistant and harder to abuse or misuse.

111. Because these detailers must adhere to scripts and talking points drafted by the Pharmaceutical Defendants, it can be reasonably inferred that most, if not all, of the Pharmaceutical Defendants' detailers made and continue to make these misrepresentations to the thousands of doctors they have visited and continue to visit. The Pharmaceutical Defendants have not corrected this misinformation.

112. The Pharmaceutical Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. On information and belief, the Pharmaceutical Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

113. The Pharmaceutical Defendants also identified doctors to serve, for payment and other remuneration, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Pharmaceutical Defendants. These speakers gave the false impression that they are providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by the Pharmaceutical Defendants. On information and belief, these

presentations conveyed misleading information, omitted material information, and failed to correct the Pharmaceutical Defendants' prior misrepresentations about the risks and benefits of opioids.

114. Each Pharmaceutical Defendant devoted and continues to devote massive resources to direct sales contacts with doctors.

115. Marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. On information and belief, more frequent prescribers are generally more likely to have received a detailing visit, and in some instances, more infrequent prescribers of opioids received a detailing visit from a Pharmaceutical Defendant's detailer and then prescribed only that Pharmaceutical Defendant's opioid products.

116. The FDA has cited at least one Pharmaceutical Defendant for deceptive promotions by its detailers and direct-to-physician marketing. In 2010, the FDA notified Allergan that certain brochures distributed by Allergan were "false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims." The FDA also found that "[t]hese violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."[15]

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[15] 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), available at http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf (last accessed March 15, 2018).

3. The Pharmaceutical Defendants Deceptively Marketed Opioids Through Unbranded Advertising Disseminated by Seemingly Independent Third Parties but Which Was Really Created by Them.

117. The Pharmaceutical Defendants also deceptively marketed opioids through unbranded advertising — i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Pharmaceutical Defendants coordinated and 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.

118. The Pharmaceutical Defendants marketed opioids 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 Pharmaceutical Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like tobacco companies, the Pharmaceutical 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.

119. The Pharmaceutical Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA.

120. The Pharmaceutical Defendants also spoke through a small circle of doctors—KOLs—who, upon information and belief, were selected, funded, and elevated by the Pharmaceutical Defendants because their public positions supported the use of opioids to treat chronic pain.

121. Pro-opioid doctors are one of the most important avenues that the Pharmaceutical Defendants use to spread their false and misleading statements about the risks and benefits of

long-term opioid use. The Pharmaceutical Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

122. For example, the New York Attorney General ("NY AG") found in its settlement with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue,[16] and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

123. Pro-opioid KOLs have admitted to making false claims about the effectiveness of opioids. Dr. Russell Portenoy received research support, consulting fees, and other compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy admitted that he "gave innumerable lectures . . . about addictions that weren't true." His lectures falsely claimed that fewer than one percent of patients would become addicted to opioids. Dr. Portenoy admitted that the primary goal was to "destigmatize" opioids, and he conceded that "[d]ata about the effectiveness of opioids does not exist." According to Dr. Portenoy, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did." Dr. Portenoy admitted that "[i]t was clearly the wrong thing to do."[17]

124. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentation, such as his claim that "the likelihood that the treatment of pain

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16 *See* New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By The Manufacturer* (August 20, 2015), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent (last accessed March 15, 2018).

17 Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, available at https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (last accessed March 15, 2018).

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 claims: "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 the person is not going to become addicted."[18]

125. 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 the 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).

126. 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

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

the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

127. 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 the Tribe's community and doctors treating members of the Tribe community.[19]

128. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and 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."[20] 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."[21]

129. The Pharmaceutical Defendants cited and promoted favorable studies or articles by their KOLs. By contrast, Pharmaceutical Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

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[19] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited March 30, 2018).

[20] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

[21] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012.

130. On information and belief, the Pharmaceutical 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 Pharmaceutical Defendants, these "Front Groups" — which include, but are not limited to, the American Pain Foundation ("APF")[22] and the American Academy of Pain Medicine — generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The evidence did not support these guidelines, materials, and programs at the time they were created, and the scientific evidence does not support them today. Indeed, they stand in marked contrast to the 2016 CDC Guideline.

131. The Pharmaceutical Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy.

132. On information and belief, these Front Groups also assisted the Pharmaceutical Defendants by responding to negative articles, by advocating against regulatory or legislative changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Pharmaceutical Defendants.

133. These Front Groups depended on the Pharmaceutical Defendants for funding and, in some cases, for survival. On information and belief, the Pharmaceutical Defendants 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 Pharmaceutical Defendants made sure that the Front Groups would generate only the messages the Pharmaceutical Defendants wanted to distribute. Despite this, the Front Groups held themselves

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[22] Dr. Portenoy was a member of the board of the APF.

out as independent and serving the needs of their members — whether patients suffering from pain or doctors treating those patients.

134. 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 the Pain & Policy Studies Group ("PPSG").[23]

135. Organizations, including the U.S. Senate Finance Committee, began to investigate APF in 2012 to determine the links, financial and otherwise, between the organization and the opioid industry.[24] The investigation revealed that APF received 90 percent of its funding from the drug and medical-device industry, and "its guides for patients, journalists and policymakers had played down the risks associated with opioid painkillers while exaggerating the benefits from the drugs." Within days, APF dissolved "due to irreparable economic circumstances."

136. 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.

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[23] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf (Last Accessed March 15, 2018).

[24] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*, Wash. Post, May 8, 2012, available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed March 15, 2018).

137. 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.

138. 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 such as Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

139. 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.

140. 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.[25]

141. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[26] 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, Allergan, and Purdue discussed treatment guidelines with doctors during individual sales visits.

142. At least 14 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 past abuse histories.[27] 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

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25 *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).

26 Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

27 *Id.*

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 Tribe'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.

143. On information and belief, the Pharmaceutical 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 Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Pharmaceutical Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers. PCF also worked to address a lack of coordination among its members and developed cohesive industry messaging.

144. On information and belief, through Front Groups and KOLs, the Pharmaceutical Defendants wrote or influenced prescribing guidelines that reflected the messaging the Pharmaceutical Defendants wanted to promote rather than scientific evidence.

145. Through these means, and likely others still concealed, the Pharmaceutical Defendants collaborated to spread deceptive messages about the risks and benefits of long-term opioid use.

E. The Pharmaceutical Defendants' Statements about the Safety of Opioids Were Patently False.

146. The Pharmaceutical Defendants' misrepresentations reinforced each other and created the dangerously misleading impressions that (a) starting patients on opioids was low-risk

because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) 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 (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.

147. Some examples of these false claims include:

a. Allergan'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 Allergan's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Allergan's 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 suggests that addiction is rare limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication is available today.[28]

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

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

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[28] Available at https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last accessed March 15, 2018).

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

f. Janssen currently runs a website, *Prescriberesponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."[29]

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 "misconceptions about opioid addiction[]." This publication is still available online.[30]

h. Consistent with the Manufacture Defendants' published marketing materials, upon information and belief, detailers for the Pharmaceutical Defendants in Wyoming have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Wyoming about 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.

148. The Pharmaceutical Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

149. The Pharmaceutical Defendants' misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

150. As noted in the 2016 CDC Guideline[31] endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term

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29 Available at, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last accessed March 15, 2018).

30 Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed March 15, 2018).

31 Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep., Mar. 18, 2016 [hereinafter 2016 CDC

for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder."

151. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for 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." (Emphasis added).[32] 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. (Emphasis added). The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

152. The Pharmaceutical Defendants have been, and are, aware that their misrepresentations about opioids are false.

153. The NY AG, 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

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Guideline], available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (last accessed March 15, 2018).

[32] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & 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/document?D=FDA-2012-P-0818-0793 (last accessed March 15, 2018); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/document?D=FDA-2014-P-0205-0006 (last accessed March 15, 2018).

40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[33] 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 NY AG 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.

154. The Pharmaceutical Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. The Pharmaceutical Defendants called this phenomenon "pseudoaddiction" — a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Portenoy — and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

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 true addiction. The 2012 edition of Responsible Opioid Prescribing remains for sale online.[34]

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

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding

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[33] Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed March 15, 2018).

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

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.

155. Pseudoaddiction is fictional. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

156. In connection with its settlement with the NY AG, Endo was forced to admit that the concept of pseudoaddiction was a sham. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that despite the fact that Endo trained its sales representative to use the concept of pseudoaddiction, "Endo's Vice President for

Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the `pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and `pseudoaddiction.'"[35]

157. The Pharmaceutical Defendants falsely instructed doctors and patients 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 Pharmaceutical Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Pharmaceutical Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, 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. On information and belief, Purdue sponsored a November 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. On information and belief, as recently as 2015, 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.

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35 *See supra* note 37, at 7.

d. On information and belief, detailers for the Pharmaceutical Defendants have touted and continue to tout to doctors in Wyoming the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

158. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by the Pharmaceutical Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies — such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse — "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy." (Emphasis added).

159. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Pharmaceutical Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

160. For example, on information and belief, a 2011 non-credit educational program 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.

161. 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.[36]

162. The Pharmaceutical Defendants deceptively minimized the significant symptoms of opioid withdrawal — which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, tremor, and tachycardia (rapid heartbeat) — and grossly understated the difficulty of tapering, particularly after long-term opioid use.

163. Contrary to the Pharmaceutical Defendants' representations, the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." (Emphasis added). The Guideline further states that "more than a few days of exposure to opioids significantly increases hazards" and "each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit."

164. The Pharmaceutical Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Pharmaceutical 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. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, Allergan's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may

[36] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed March 15, 2018).

become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction."

b. Cephalon and Purdue 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 are therefore the most appropriate treatment for severe pain. This guide is still available online.[37]

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."[38]

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

f. On 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, even unlimited ones, but it did not disclose the risks from high opioid dosages. This publication is still available online.[39]

h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least

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[37] Available at, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last accessed March 15, 2018).

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

[39] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed March 15, 2018).

2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Front Group APF and others argued to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[40]

j. On information and belief, Purdue's detailers have told doctors in Wyoming that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

165. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, 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 higher opioid dosage." 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." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

166. The Pharmaceutical Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse.

167. These abuse deterrent formulations (AD opioids) purportedly are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids can be defeated — often quickly and easily — by those determined to do so. The 2016 CDC Guideline state that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the

[40] Brief of the APF *et al.* in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir. Sept. 8, 2005).

technologies—even when they work—do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long term as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[41]

168. Despite this lack of evidence, the Pharmaceutical Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

169. For example, Endo has marketed Opana ER[42] as tamper- or crush-resistant and less prone to misuse and abuse even though: (1) on information and belief, the FDA warned in a 2013 letter that there was no evidence that Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (2) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Nonetheless, Endo's advertisements for Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And on information and belief, detailers for Endo have informed doctors that Opana ER is harder to abuse.

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[41] Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public Integrity (Dec. 15, 2016), available at https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution (last accessed March 15, 2018).

[42] Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market. Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm (last accessed March 15, 2015).

170. In its 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

171. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids — i.e., reformulated OxyContin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, beginning in 2013 and continuing today, detailers from Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, on information and belief, these detailers: (1) falsely claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) falsely claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) falsely claim Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

172. These statements and omissions by Purdue are false and misleading. Purdue knew and should have known that reformulated OxyContin is not better at tamper resistance than the original OxyContin and is still regularly tampered with and abused. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent

that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[43] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.[44]

173. The development, marketing, and sale of AD opioids is a continuation of the Pharmaceutical Defendants' strategy to use misinformation to drive profit. The Pharmaceutical Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit.

F. The Pharmaceutical Defendants Misrepresented the Benefits of Chronic Opioid Therapy.

174. To convince doctors and patients that opioids should be used to treat chronic pain, the Pharmaceutical Defendants also had to persuade them that there was a significant upside to long-term opioid use.

175. The 2016 CDC Guideline makes clear, there is "insufficient evidence to determine long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[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

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[43] Cicero, Theodore J., and Matthew S. Ellis, "Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin" (2015) 72.5 *JAMA Psychiatry* 424-430.

[44] See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose epidemic*, Business Insider, Mar. 14, 2016, available at http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3 (last accessed March 15, 2018).

randomized trials < 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

176. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."

177. Despite this, the Pharmaceutical 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. Not only have the Pharmaceutical Defendants failed to correct these false and misleading claims, they continue to make them today.

178. For example, the Pharmaceutical Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, Allergan distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients 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. On information and belief, 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 and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

d. Responsible Opioid Prescribing (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

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

f. On information and belief, Endo's NIPC website *painknowledge.com* claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy.

g. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

h. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide is still available online today.

i. In a 2015 video on Forbes.com[45] discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

179. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added). The CDC reinforced this conclusion throughout its 2016 Guideline:

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[45] Matthew Harper, *Why Supposedly Abuse-Proof Pills Won't Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at https://www.forbes.com/sites/matthewherper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1 (last accessed March 15, 2018).

a. "No 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 . . . ."

b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."

c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

180. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

181. The 2016 CDC Guideline was not the first time a federal agency repudiated the Pharmaceutical Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Allergan that "[w]e 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 ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[46] And upon information and belief, in 2008 the FDA sent a warning letter to an opioid manufacturer, making it publicly 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."

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[46] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf (last accessed March 15, 2018).

182. The Pharmaceutical Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Pharmaceutical Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Pharmaceutical Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.[47] The Pharmaceutical Defendants have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Pharmaceutical Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. For example, the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

183. For example, 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 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

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[47] *See, e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at, https://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf (last accessed March 15, 2018).

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.

184. 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.

185. Despite this, on information and belief, 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, or safe.[48] 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.

186. 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. For example:

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[48] *See* 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-civ-860.html (last accessed March 15, 2018).

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.

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

188. On information and belief, the Pharmaceutical Defendants coordinated their messaging through national and regional sales and speaker trainings and coordinated advertisements and marketing materials.

189. Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Pharmaceutical 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 Pharmaceutical Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

190. Finally, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Pharmaceutical Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the Pharmaceutical 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 Tribe.

191. The Pharmaceutical Defendants' efforts to artificially increase the number of opioid prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since

1999 and has increased in parallel with [opioid] overdoses."[49] Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[50] Accordingly, the Pharmaceutical Defendants' false and misleading statements directly caused the current opioid epidemic.

G. All Defendants Created an Illicit Market for Opioids.

192. In addition to the allegations above, all Defendants played a role in the creation of an illicit market for prescription opioids, further fueling the opioid epidemic.

193. Each participant in the supply chain shares the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of distribution or use to an illegitimate channel of distribution or use.

194. Diversion can occur at any point in the opioid supply chain.

195. For example, diversion can occur at the wholesale level of distribution when distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

196. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose

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[49] Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm (last accessed March 15, 2018).

[50] *Id.*

or not in the usual course of practice. Some of the signs that a prescription may have been issued for an illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from different doctors (known as doctor shopping), when they travel great distances between the doctor or their residence and the pharmacy to get the prescription filled, when they present multiple prescriptions for the largest dose of more than one controlled substance, or when there are other "red flags" surrounding the transaction. These red flags should trigger closer scrutiny of the prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication to treat a legitimate medical condition.

197. Diversion occurs through the use of stolen or forged prescriptions or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses. Opioids can also be diverted when stolen by employees or others.

198. Opioid diversion occurs at an alarming rate in the United States.

199. Each participant in the supply chain, including each Defendant, has a common law duty to prevent diversion by using reasonable care under the circumstances. This includes a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

200. In addition to their common law duties, Defendants are subject to the statutory requirements of the Controlled Substances Act, 21 U.S.C. § 801 et seq. (the "CSA"), and its implementing regulations. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572.

201. Defendants' repeated and prolific violations of these requirements show that they have acted with willful disregard for the Tribe, tribal community, and the people therein.

202. The CSA imposes a legal framework for the distribution and dispensing of controlled substances. This framework acts as a system of checks and balances from the manufacturing level through delivery of the controlled substance to the patient or ultimate user.

203. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA.

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

205. Under the CSA, anyone authorized to handle controlled substances must track shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from the point of manufacture through distribution to the point of sale. ARCOS accumulates data on distributors' controlled substances and transactions, which are then used to identify diversion. Each person or entity registered to distribute ARCOS reportable controlled substances, including opioids, must report each acquisition and distribution transaction to the DEA. *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete,

accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of.

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

1. The Distributor Defendants Negligently Failed to Control the Flow of Opioids to the Tribe Through Illicit Channels.

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

208. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring and the responsibilities and obligations of registrants to prevent diversion.

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

210. Suspicious orders must be reported when discovered. Registrants must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

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

212. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

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

214. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.[51] The DEA has repeatedly taken action to attempt to

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[51] Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post, Oct. 15, 2017, available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/ (last accessed March 15, 2018); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post, Oct. 22, 2016, available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.f94d865524e8 (last accessed March 15, 2018).

force compliance, including 178 registrant actions between 2008 and 2012, 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions involving immediate suspension orders.[52] The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined $150,000,000.[53]

b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.

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

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

e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in

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52 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), available at https://oig.justice.gov/reports/2014/e1403.pdf (last accessed March 15, 2018).

53 Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin. and the McKesson Corp. (Jan. 17, 2017), available at https://www.justice.gov/opa/press-release/file/928476/download (last accessed March 15, 2018).

Swedesboro, New Jersey, for failure to maintain effective controls against diversion.

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

g. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States.[54]

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

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

j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act.[55]

k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

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

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[54] Lenny Bernstein and Scott Higham, *Cardinal Health fined $44 million for opioid reporting violations*, Wash. Post, Jan. 11, 2017, available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html (last accessed March 15, 2018).

[55] Press Release, United States Dep't of Justice, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act (last accessed March 15, 2018).

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

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

216. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid diversion created an enormous black market for prescription opioids, which market extended to the Tribe and its members. Each Distributor Defendant knew or should have known that the opioids reaching the Tribe were not being consumed for medical purposes and that the amount of opioids flowing to the Tribe was far in excess of what could be consumed for medically necessary purposes.

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

218. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing the areas around the Tribe to perform due diligence inspections to

ensure that the controlled substances the Distributor Defendants had furnished were not being diverted to illegal uses.

219. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the areas around the Tribe, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

220. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market in and around the Tribe with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

221. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death. It is also reasonably foreseeable that many of these injuries will be suffered by tribal members, and that the costs of these injuries will be borne by the Tribe.

222. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic faced by the Tribe, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

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

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

225. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into the Tribe. The Distributor Defendants knew that the Tribe would be unjustly forced to bear the costs of these injuries and damages.

226. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to relatively small communities primarily serving tribal members showed an intentional or reckless disregard for the safety of the Tribe and their members. Their conduct poses a continuing threat to the health, safety, and welfare of the Tribe.

227. The federal, state and tribal laws at issue here are public safety laws.

228. The Distributor Defendants' violations constitute prima facie evidence of negligence under applicable law.

2. The Pharmaceutical Defendants Negligently Failed to Control the Flow of Opioids to the Tribe Through Illicit Channels.

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

230. Like the Distributor Defendants, the Pharmaceutical Defendants are required to design and operate a system to detect suspicious orders, and to report such orders to law enforcement. (See 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823). The Pharmaceutical Defendants have not done so.

231. On information and belief, for over a decade the Pharmaceutical Defendants have been able to track the distribution and prescribing of their opioids down to the retail and prescriber level. Thus, the Pharmaceutical Defendants had actual knowledge of the prescribing practices of doctors, including red flags indicating diversion. The Pharmaceutical Defendants did not report those red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the Pharmaceutical Defendants breached their duties under federal and other applicable law.

232. The Pharmaceutical 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 Pharmaceutical Defendants knew — the volume, frequency, and pattern of opioid orders being placed and filled. The Pharmaceutical Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

233. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law (21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(a)(1)), fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[56] Among the allegations resolved by the

[56] *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

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."[57] Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.[58]

234. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors and could identify doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs.[59] 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

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Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders (last accessed March 15, 2018).

[57] *Id.* (internal quotation omitted).

[58] 2017 Mallinckrodt MOA at p. 2-3.

[59] Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. Times, August 11, 2013, available at http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811 (last accessed March 15, 2018).

generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*,[60] 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 until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

235. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.[61]

236. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a *Los Angeles Times* article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it."[62] The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

237. 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 NY

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60 Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminal and addicts. What the drugmaker knew*, L.A. Times, July 10, 2016, available at http://www.latimes.com/projects/la-me-oxycontin-part2/ (last accessed March 15, 2018).

61 *See* NY Purdue Settlement, at 6-7, available at http://www.ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf (last visited March 15, 2018).

62 Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. Times, August 11, 2013, available at http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811 (last accessed March 15, 2018).

AG 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; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegally prescribing opioids, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

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

239. The Pharmaceutical Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into the Tribe's community.

H. The Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.

240. As the Pharmaceutical Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and the sale of their products—and the rates of opioid-related substance abuse, hospitalization, and death within the Tribe and across the nation. Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of opioids into communities like the Tribe's community, fueling the epidemic.

241. 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."[63]

242. Opioids 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.[64]

243. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[65]

244. The increased abuse of prescription opioids—along with growing sales—has contributed to a large number of overdoses and deaths.

245. As shown above, the opioid epidemic has escalated in the Tribe's community with devastating effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants' increased distribution of opioids.

246. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to the Tribe's community and areas from which opioids are being diverted to the Tribe, has caused the opioid epidemic to include heroin addiction, abuse, and death.

247. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the Tribe's community.

248. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the Tribe's community.

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63 *See* Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

64 Volkow & McLellan, *supra* note 1.

65 Califf, *supra* note 2.

249. 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 in the Tribe's community.

250. 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 morality in the Tribe's community. This diversion and the resulting epidemic are direct causes of foreseeable harms incurred by the Tribe and members of the Tribe's community.

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

252. The Tribe seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

253. The Tribe seeks economic damages from the Defendants to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.

254. 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."[66]

255. 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 need of patients experiencing pain.[67]

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66 Rudd, *supra* note 53.

67 *See* Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf (last accessed March 15, 2018).

256. The community-based problems require community-based solutions that have been limited by budgetary constraints.

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

258. The opioid epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The 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.

259. The Defendants have abandoned their duties imposed by the law, have taken advantage of a lack of DEA enforcement, and have abused the privilege of distributing controlled substances in the Tribe's community.

260. In the course of conduct described in this Complaint, Defendants have acted with oppression, fraud, and malice, actual and presumed.

I. The Statutes of Limitations Are Tolled and Defendants Are Estopped from Asserting Statutes of Limitations as Defenses.

261. Defendants' conduct has continued from the early 1990s through today, and is still ongoing. 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.

262. 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 that they were undertaking efforts to comply with their obligations under the controlled substances laws, all with the goal of continuing to generate profits.

263. 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."[68]

264. 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."[69]

265. Defendants, through their trade associations, filed an amicus brief that represented that Defendants took their duties seriously, complied with their statutory and regulatory responsibilities, and monitored suspicious orders using advanced technology.[70]

266. Defendants purposely concealed their wrongful conduct, including by assuring the public and governmental authorities that they were complying with their obligations and were acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their

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[68] 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, available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.7f6f1a87e2ca (last accessed March 15, 2018)

[69] 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, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html (last accessed March 15, 2018).

[70] Br. for Healthcare Distribution Mgmt. Ass'n and Nat'l Ass'n of Chain Drug Stores as Amici Curiae in Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4, 2016).

behavior by providing the public with false information about opioids and have continued to use Front Groups and third parties to minimize the risks of Defendants' conduct.

267. 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.

268. Defendants also lobbied Congress and actively attempted to halt DEA investigations and enforcement actions and to subvert the ability of agencies to regulate their conduct.[71] As a result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a distributor's license was raised.

269. In addition, the Defendants fraudulently attempted to convince the public that they were complying with their legal obligations and working to curb the opioid epidemic.

270. Because the Defendants concealed the facts surrounding the opioid epidemic, the Tribe did not know if the existence or scope of the Defendants' misconduct, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

271. Defendants intended that their false statements and omissions be relied upon, including by the Tribe, its community, and its members.

272. Defendants knew of their wrongful acts and had material information pertinent to their discovery, but concealed that information from the public, including the Tribe, its community, and its members. Only Defendants knew of their widespread misinformation campaign and of their repeated, intentional failures to prevent opioid diversion.

273. Defendants cannot claim prejudice due to a late filing because this suit was filed upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the opioid crisis have only recently come to light.

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71 *See* Higham and Bernstein, *supra* note 55.

274. Defendants had actual knowledge that their conduct was deceptive, and they intended it to be deceptive.

275. The Tribe was unable to obtain vital information regarding these claims absent any fault or lack of diligence on the Tribe's part.

J. The Impact of Opioid Abuse on the Tribe.

276. Defendants' creation, through false and misleading advertising and a failure to prevent diversion, of a virtually limitless opioid market has significantly harmed tribal communities and resulted in an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

277. American Indians suffer the highest per capita rate of opioid overdoses.[72]

278. The impact on American Indian children is particularly devastating. The CDC reported that approximately 1 in 10 American Indian youths ages 12 or older used prescription opioids for nonmedical purposes in 2012, double the rate for white youth.[73]

279. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency room visits have also skyrocketed.[74] For every opioid overdose death, there are 10 treatment admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825 nonmedical users of opioids.[75]

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[72] National Congress of American Indians, *Reflecting on a Crisis Curbing Opioid Abuse in Communities* (Oct. 2016), available at http://www.ncai.org/policy-research-center/research-data/prc-publications/Opioid_Brief.pdf (last accessed March 15, 2018).

[73] *Id.*

[74] Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one year*, LA Times, Oct. 27, 2014, available at http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html (last accessed March 15, 2018).

[75] Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa, *The Opioid Crisis in Indian Country*, at 37, available at https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf (last accessed

280. The fact that American Indian teens are able to easily obtain prescription opioids through the black market created by opioid diversion highlights the direct impact on the Tribe from Defendants' actions and inactions.

281. Even the Tribe's youngest members bear the consequences of the opioid abuse epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.[76] Many tribal women have become addicted to prescription opioids and have used these drugs during their pregnancies. As a result, many tribal infants suffer from opioid withdrawal and Neonatal Abstinence Syndrome ("NAS").[77]

282. Infants suffering from NAS are separated from their families and placed into the custody of the tribal child welfare services or receive other governmental services so they can be afforded medical treatment and be protected from drug-addicted parents.

283. The impact of NAS can be life-long. Most NAS infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require an emergency evacuation for care to save the infant's life. Such emergency transportation costs the Tribe thousands of dollars for each occurrence.

284. Many NAS infants have short-term and long-term developmental issues that prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from

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March 15, 2018); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid Overdoses, US., 2010-2014*, Am. J. of Preventive Medicine, Jan. 2018, available at http://www.ajpmonline.org/article/S0749-3797(17)30494-4/pdf (last visited March 15, 2018).

[76] Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of Health, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/ (last accessed March 15, 2018).

[77] Jean Y, Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence Syndrome*, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6609a2.htm (last accessed March 15, 2018).

vision and digestive issues; some are unable to attend full days of school. These disabilities follow these children through elementary school and beyond.

285. Pregnant American Indian women are up to 8.7 times[78] more likely to be diagnosed with opioid dependency or abuse compared to the next highest demographic, and in some communities upwards of 1 in 10 pregnant American Indian women has a diagnosis of opioid dependency or abuse.[79]

286. Many of the parents of these children continue to relapse into prescription opioid use and abuse. As a result, many of these children are placed in foster care or adopted.

287. Opioid diversion also contributes to a range of social problems including physical and mental consequences, crime, delinquency, and mortality. Opioid abuse has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids. Other adverse social outcomes include child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage, unemployment, and despair. More and more tribal resources are needed to combat these problems, leaving a diminished pool of already-scarce resources to devote to positive societal causes like education, cultural preservation, and other social programs. The prescription opioid crisis diminishes the Tribe's available workforce, decreases productivity, increases poverty, and requires greater governmental expenditures by the Tribe. It also undermines the ability of the Tribe to self-govern and to maintain and develop economic independence.

288. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. Some will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who

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78 DuPuis, *supra* note 79, at 64.

79 *Id.*

continue to take opioids, some will overdose — some fatally, some not. Others will die prematurely from related causes — falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease. The opioid epidemic undermines the ability of the Tribe to self-govern and to maintain and develop economic independence.

289. While the use of opioids has taken an enormous toll on the Tribe and its people, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like the Pharmaceutical Defendants. Indeed, on information and belief, each Defendant experienced a material increase in sales, revenue, and profits from the unlawful and unfair conduct described above.

V. CAUSES OF ACTION

COUNT I: Public Nuisance
(Against all Defendants)

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

291. Tribal law recognizes the concept of public nuisance. Specifically, the Northern Arapaho Code § 20-5-511(a) provides that: "No person shall act in such a manner...so as to injure or endanger the safety, health, comfort or property of his neighbors."

292. Similarly, the common law of nuisance prohibits persons from endangering the public through actions that affect safety, health, comfort, peace or property of other individuals. See e.g. Restatement (Second) of Torts, § 821B(1). Wyoming law also authorizes local ordinances to prohibit public nuisance. Wyoming Stat. § 35-10-408.

293. Plaintiff and the residents of Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

294. Plaintiff alleges that Defendants have violated their rights by creating a public nuisance through their negligent actions in manufacturing, distributing and promoting opioid medications.

295. Each Defendant is liable for public nuisance because its failure to exercise due care in the manufacture, distribution and promotion of opioid medications has caused an unreasonable interference with a right of the public and specifically the members of the Tribe to enjoy safety, health, comfort, peace or property.

296. In addition, Defendants have acted in an intentional, wrongful or illegal manner such as to create an absolute nuisance.

297. Specifically, Defendants intentionally, unlawfully, and recklessly manufacture, market, distribute, and sell prescription opioids causing widespread distribution of prescription opioids in and/or to Plaintiff's Community, resulting in addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's Community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community with direct costs to Plaintiff's Community.

298. Defendants have also unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Plaintiff's Community and its residents.

299. Specifically Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. 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, and constitute intentional and/or unlawful activities.

300. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

301. Defendants' conduct in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally Plaintiff's Community is of a continuing nature.

302. 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.

303. A violation of any rule or law controlling the distribution of a drug of abuse in Plaintiff's Community and the State is a public nuisance.

304. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

305. 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.

306. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

307. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare, and the public s ability to be free from disturbance and reasonable apprehension of danger to person and property.

308. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public s ability to be free from disturbance and reasonable apprehension of danger to person and property.

309. 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 law. See, e.g., 21 U.S.C. § 812 (b)(2).

310. 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 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.

311. 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.

312. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Plaintiff's Community not only causes deaths and injuries, but also creates a palpable climate of fear among residents in Plaintiff's Community where opioid diversion, abuse, addiction are prevalent and where diverted opioids tend to be used frequently.

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

314. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

315. 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 Plaintiff and to Plaintiff's Community in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

316. 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.

317. Defendants' conduct is a direct and proximate cause of deaths and injuries to the residents of Plaintiff's Community, costs borne by Plaintiff's Community and the Plaintiff, and a

significant and unreasonable interference 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.

318. 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, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

319. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Plaintiff's Community, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids, or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

320. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants' distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against

diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in Plaintiff's Community.

321. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

322. The damages available to the Plaintiff include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance which the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

323. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Community have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The Plaintiff here seeks recovery for its own harm.

324. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because its damages include, *inter alia*, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

325. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

326. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* abatement, compensatory damages, and punitive damages from the Defendants for the creation of a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

327. Defendants' intentional and unlawful actions and omissions and unreasonable interference with a right common to the public are of a continuing nature.

328. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the Plaintiff's community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because inter alia these drugs are defined under federal, state, and tribal law as substances posing a high potential for abuse and severe addiction. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

329. The public nuisance created by Defendants' actions is substantial and unreasonable - it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is limited to the following:

330. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

331. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

332. Even those residents of Plaintiff's Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties

and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

333. The opioid epidemic has increased health care costs.

334. Employers have lost the value of productive and healthy employees.

335. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

336. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants' led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

337. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.

338. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the Plaintiff's Community.

339. Defendants' interference with the comfortable enjoyment of life in the Plaintiff's Community is unreasonable because there is little social utility to opioid diversion and abuse,

and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

340. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because its damages include *inter alia* health services and law enforcement expenditures, as described in this Complaint.

341. Plaintiff seeks economic losses (direct, incidental, and/or consequential pecuniary losses) resulting from the public nuisance created by Defendants' fraudulent activity and fraudulent misrepresentations. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

342. Plaintiff seeks all legal and equitable relief as allowed by law for the public nuisance created by Defendants, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT II: RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. §1961 *et seq.*
(Against all Defendants)

343. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

344. Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, Defendants were each a "person" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, a legal or beneficial interest in property.

345. For over a decade, the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the Defendants operated and continue to operate within the closed system created by the CSA. The CSA restricts the Defendants' ability to manufacture or distribute Schedule II controlled substances like opioids by requiring Defendants to maintain effective controls against diversion, design and operate a system to identify suspicious orders and halt such unlawful sales and report them to the DEA, and to make sales within a limited quota set by the DEA.

346. The closed system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II controlled substances, including opioids.

347. Finding it impossible to achieve their increasing sales ambitions through legal means, the Defendants systematically and fraudulently violated their statutory duties to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders and to notify the DEA of suspicious orders. The Defendants repeatedly engaged in unlawful sales of painkillers, which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.

348. An association-in-fact enterprise between the Distributor Defendants and the Pharmaceutical Defendants hatched this illegal scheme, and each Defendant participated in the scheme's execution, the purpose of which was to engage in the unlawful sale of opioids while

deceiving the public and regulators into believing that the Defendants were faithfully fulfilling their obligations. As a direct result of the Defendants' scheme, they were able to extract billions of dollars in revenue while entities like the Tribe experienced millions of dollars in injuries caused by the foreseeable—and inevitable—consequences of the opioid epidemic Defendants created.

349. Alternatively, Defendants were also members of a legal entity enterprise. The Healthcare Distribution Alliance ("HDA")[80] is a distinct legal entity that qualifies as an enterprise under 18 U.S.C. § 1961(4). On information and belief, each Defendant is a member, participant, and/or sponsor of the HDA. Defendants utilized the HDA to conduct the RICO Enterprise. Each of the Defendants is a legal entity separate from the HDA.

350. The RICO Enterprise: Congress enacted the CSA to create a closed system for distribution of controlled substances. Congress was concerned with the diversion of drugs out of legitimate channels of distribution. Moreover, Congress specifically designed the closed system to ensure that there are multiple ways of identifying and preventing diversion.

351. A central component of the closed system was Congress's directive that the DEA determine quotas of each basic class of Schedule I and Schedule II controlled substances each year.

352. The Defendants operated as an association-in-fact to unlawfully increase sales and revenues in order to unlawfully increase the quotas set by the DEA, which in turn allowed them to collectively profit from distributing a greater pool of opioids each year. Each member of the Rico Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding profits generated by the scheme.

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[80] Health Distribution Alliance, *History*, Health Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history (last accessed March 15, 2018).

353. The Defendants also engaged in lobbying efforts against the DEA's authority to investigate and hold responsible those who failed in their duty to prevent diversion. The Ensuring Patient Access and Effective Drug Enforcement Act was the result of an effort by the Defendants to reduce the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. On information and belief, the Pain Care Forum and its members poured millions of dollars into lobbying efforts while the FDA devoted over a million dollars a year to lobbying.

354. The RICO Enterprise functioned by selling prescription opioids in interstate commerce in violation of the Defendants' legal obligations to maintain effective controls against opioid diversion.

355. Each Defendant communicated with other Defendants, shared information on a regular basis, and participated in joint lobbying efforts, trade industry organizations, contractual relationships, and other coordination of activities to effect the RICO Scheme. The contractual relationships included, on information and belief, rebates and/or chargebacks on opioid sales and security arrangements. All told, from 2006 to 2015, the Defendants worked together through the Pain Care Forum to spend over $740 million in lobbying across the country to enable the RICO Enterprise.[81]

356. The Defendants disseminated false and misleading statements to the public regarding the safety of prescription opioids for chronic pain relief. The Defendants also falsely disseminated statements that they were complying with their obligations to maintain effective controls against the diversion of their prescription opioids.

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[81] *See* Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity, https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (last accessed March 30, 2018).

357. The Defendants refused to identify, investigate, or report suspicious orders despite their actual knowledge of drug diversion rings.

358. The Defendants worked together to ensure that opioid production quotas continued to increase, allowing them to generate more and more profits from the RICO Enterprise.

359. The RICO Scheme: Participants took intentional and affirmative steps to conceal the Scheme, including by using unbranded advertisement, third parties, and the Front Groups to disguise the source of the participants' fraudulent statements and to increase the effectiveness of the participants' misinformation campaign. These actions were taken to ensure that the RICO Scheme continued to be effective.

360. The pattern of racketeering activity: Each time that a participant in the RICO Scheme distributed a false statement by mail or wire, it committed a separate act of mail fraud or wire fraud under 18 U.S.C. §§ 1341 and 1341, respectively.

361. The Defendants used, or caused to be used, thousands of interstate mail and wire communications through virtually uniform misrepresentations, concealments, and material omissions regarding the safety of opioids and their compliance with the CSA's anti-diversion requirements. The Defendants committed this continuous pattern of racketeering activity intentionally and knowingly with the intent to advance the RICO Enterprise.

362. The Defendants also conducted a pattern of racketeering by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance punishable under any law of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false

information or omit any material information from any application, report, record or other document required to be made, kept, or filed, a violation of which is a felony.

363. Each of the Defendants was a registrant under the CSA and was required to maintain effective diversion controls and investigate and report suspicious orders.

364. The Defendants knowingly and routinely furnished false, misleading, or incomplete information in their reports to the DEA and in their applications for production quotas. As described herein, the Defendants did unlawfully, knowingly, and intentionally conspire, confederate, and agree with each other to engage in the scheme described herein, in violation of 18 U.S.C. § 1962(c) and (d).

365. As a result of the conduct by the Defendants, the Tribe has been and continues to be injured in an amount to be determined in this litigation.

366. Pursuant to 18 U.S.C. § 1964(c), the Tribe is entitled to recover threefold its damages, costs, and attorney's fees. In addition, the Tribe is entitled to injunctive relief to enjoin the racketeering activity.

COUNT III: LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)
(Against All Defendants)

367. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

368. The Lanham Act provides, in pertinent part:

> (1) Any person who, on or in connection with any good or services, or any container for goods, uses in commerce any word, terms, 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 what, which —
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> . . .
>
> (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 how believes that he or she is or is likely to be damaged by such act.

369. As alleged in Paragraphs 44 — 274 of this Complaint, the Pharmaceutical Defendants committed repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in connection with the sale of goods and services.

370. The Pharmaceutical Defendants engaged in a false and misleading advertising campaign designed to deceive doctors and the public into believing that opioids were safe for the treatment of chronic pain.

371. The Tribe is entitled to legal and equitable relief, including injunctive relief, disgorgement of profits, and damages in an amount to be determined in this litigation.

COUNT IV: DECEPTIVE TRADE PRACTICES
(Against All Defendants)

372. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

373. The Defendants knowingly used or employed—and continue to use and employ—a deceptive act or practice, fraud, false pretense, false promises, or misrepresentation to conceal, suppress, or omit any material fact in connection with the sale or advertisement of prescription opioids, as more fully described in this Complaint, in violation of applicable law.

374. The Pharmaceutical Defendants' violations directly and proximately caused the Tribe to suffer economic damages in an amount to be determined in this litigation.

COUNT V: FRAUD
(Against all Defendants)

375. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

376. The Defendants made fraudulent misrepresentations and omissions of material fact, as more fully described in this Complaint.

377. Those misrepresentations and omissions were known to be untrue by the Defendants, or were recklessly made.

378. The Defendants made those misrepresentations and omissions in an intentional effort to deceive and to induce doctors and patients to prescribe and use prescription opioids for chronic pain relief, despite the Defendants' knowledge of the dangers of such use of prescription opioids.

379. The Defendants continued making those misrepresentations, and failed to correct those material omissions, despite repeated regulatory settlements and publications demonstrating the false nature of the Defendants' claims.

380. Doctors, including those serving the Tribe and its members, relied on the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.

381. Patients, including members of the Tribe, relied on the Defendants' misrepresentations and omissions in taking prescription opioids for chronic pain relief.

382. The Tribe has been damaged by the Defendants' misrepresentations in an amount to be determined in this litigation.

COUNT VI: NEGLIGENCE AND GROSS NEGLIGENCE
(Against all Defendants)

383. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

384. All Defendants had a legal duty to act with the exercise of ordinary care or skill to prevent injury to another under the common law and statutes.

385. All Defendants voluntarily undertook a legal duty to prevent the diversion of prescription opioids by engaging in the distribution of prescription opioids and by making public promises to prevent the diversion of prescription opioids.

386. All Defendants knew of the serious problem posed by prescription opioid diversion and were under a legal obligation to take reasonable steps to prevent diversion.

387. All Defendants knew of the highly addictive nature of prescription opioids and knew of the high likelihood of foreseeable harm to patients and communities, including the Tribe, from prescription opioid diversion.

388. All Defendants breached their duties when they failed to act with reasonable care to prevent the diversion of prescription opioids.

389. Defendants' breaches of their duty of care foreseeably and proximately caused damage to the Tribe.

390. The Tribe is entitled to damages from Defendants in an amount to be determined in this litigation.

COUNT VII: NEGLIGENCE PER SE
(Against all Defendants)

391. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

392. All Defendants had a duty under the CSA and its implementing regulations to prevent the diversion of prescription opioids.

393. The CSA and its implementing regulations were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

394. Further, under the Federal Food, Drug, and Cosmetic Act ("the FDCA"), all Defendants had a duty to prevent the introduction or delivery into interstate commerce of any drug that is adulterated or misbranded. 21 USC § 331(a).

395. Drug advertising is considered misbranded if any statement of fact (or omission of information) is misleading as to a material issue. 21 USC § 321(n). The FDA further requires that all drug advertisements contain balanced, truthful, and scientifically supported statements of fact. 21 C.F.R. § 202.1. It is a violation of FDA regulations to fail to reveal facts that are material in light of other representations made or suggested, and with respect to the consequences that may result from the use of the drug. 21 C.F.R. § 1.21.

396. The FDCA and these FDA regulations were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

397. All Defendants engaged in misrepresentation and fraud, and aided and abetted the use of misrepresentation and fraud, in the distribution of prescription opioids in Wyoming and the Tribe's community.

398. Further, as alleged in this Complaint, Defendants misbranded their drugs by providing false, misleading, and/or incomplete information about the risks and benefits of their products.

399. As such, all Defendants failed to perform their statutory and regulatory duties under the CSA, FDCA, and other applicable laws and regulations.

400. Defendants' breach of these duties of care foreseeably and proximately caused damage to the Tribe.

401. The Tribe is entitled to damages from Defendants in an amount to be determined in this litigation.

COUNT VIII: UNJUST ENRICHMENT
(Against all Defendants)

402. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

403. Defendants received a benefit in the form of billions of dollars in revenue from the sale of prescription opioids to treat chronic pain, while fully aware that these drugs were not appropriate for such use because they would cause harm and financial burdens to the individuals and the public so exposed, including Plaintiff.

404. Defendants received a benefit in the form of billions of dollars in revenue from negligent, reckless or illegal distribution of opioid medications, while fully aware that these distribution practices would cause harm and financial burdens to the individuals and the public so exposed, including Plaintiff.

405. Defendants retained the benefit of billions of dollars in revenue as described above at the at the expense of the individuals and the public, including the Plaintiff Tribe, who has borne—and who continues to bear—the economic and social costs of Defendants' scheme.

406. Equity prohibits Defendants' retention of this benefit while burdening Plaintiff with the obligation to compensate for and remediate the harm caused by Defendants' conduct.

407. The Plaintiff Tribe is therefore entitled in equity to recover from Defendants' prescription opioid profits the amounts the Tribe has spent and will have to spend in the future to address the effects of Defendants' actions.

COUNT IX: CIVIL CONSPIRACY
Against all Defendants

408. The Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

409. The Defendants agreed to engage in a campaign to flood the market with false and misleading information about the safety of prescription opioid use for the treatment of chronic pain, to evade controls on opioid diversion, and to increase opioid quotas.

410. The Defendants did so in an effort to profit from the increased sales of prescription opioids.

411. Each Defendant made false or misleading statements directly and through third parties to further the objectives of their conspiracy.

412. The Tribe was directly and proximately harmed by the Defendants' civil conspiracy in an amount to be determined in this litigation.

PRAYER FOR RELIEF

WHEREFORE, the Tribe respectfully requests judgment in its favor granting the following relief:

a) Judgement in favor of the Tribe against each of the Defendants;

b) Actual and consequential damages in an amount to be determined at trial;

c) An award of all damages resulting from Defendants' violation of 18 U.S.C. § 1962(c) and (d), including prejudgment interest and treble damages pursuant to 18 U.S.C. § 1962(c);

d) Disgorgement of revenues and profits;

e) Past and future expenses incurred due to the public nuisance caused by the opioid epidemic;

f) Creation of an "abatement fund" to address the public nuisance;

g) Compensatory damages including (a) costs for providing medical care, therapy and treatment for patients suffering opioid-related addiction or disease, overdose or deaths; (b) costs for addiction treatment, counseling, and rehabilitation services; (c) costs for treatment of infants born with opioid-related medical conditions; (d) costs for care of children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with law enforcement and public safety relating to the opioid epidemic, and (f) other governmental costs as proven at trial related to the opioid crisis;

h) Punitive damages;

i) Injunctive relief;

j) Attorney's fees, costs and expenses, as provided by 18 U.S.C. § 1964(c) or other provisions of statutory or common law;

k) Pre- and post-judgment interest; and

l) Any other relief deemed just, proper, and/or equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial on all claims so triable.

RESPECTFULLY SUBMITTED,

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