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

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** **THE MUSCOGEE (CREEK) NATION,** **PLAINTIFF,** **v.** **PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC.; ALLERGAN FINANCE LLC; WATSON LABORATORIES, INC.; TEVA PHARMACEUTICALS USA, INC.; AMNEAL PHARMACEUTICALS, INC.; KVK-TECH, INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; CARDINAL HEALTH 110, LLC; AMERISOURCEBERGEN CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; MORRIS & DICKSON CO., LLC; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN CO.; WAL-MART STORES, INC.; SAJ DISTRIBUTORS; GCP PHARMA LLC; ANDA PHARMACEUTICALS, INC.; ANDA, INC.; OMNICARE DISTRIBUTION CENTER LLC; SMITH DRUG COMPANY; THE HARVARD DRUG GROUP, LLC; PHARMACY BUYING ASSOCIATION; H.D. SMITH, LLC; CVS HEALTH CORPORATION; CVS PHARMACY INC.; OKLAHOMA CVS PHARMACY, LLC; THE DRUG WAREHOUSE; MAY'S DRUG STORE; REASOR'S LLC; MED-X CORPORATION; ECONOMY DISCOUNT PHARMACY; ECONOMY PHARMACY, INC.; ECONOMY PHARMACY EXPRESS; CITY DRUG CO.; CITY DRUG OF COWETA, INC.; SPOON DRUGS, INC.; CAREFIRST PHARMACY, INC.; CITYPLEX PHARMACY; COUCH PHARMACY ON SHERIDAN; ERNIE'S PHARMACY & WELLNESS CENTER, INC.; FREELAND BROWN PHARMACY, INC.; GADDY DISCOUNT DRUG, INC.; GETMAN-APOTHECARY SHOPPE, INC.; LANGSAM HEALTH SERVICES, LLC; M & D STAR DRUG, INC.; MED-ECON DRUG, INC.; OLYMPIA PHARMACY; PIPPENGER PHARMACIES LLC; AND ROGERS DRUG CO. INC.,** **DEFENDANTS.**	**MDL No. 2804** **Master Docket No.: 1:17-MD-02804-DAP** **Hon. Judge Dan A. Polster** **Case No.: 1:18-op-45459-DAP** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT

TABLE OF CONTENTS

Page

Plaintiff, the Muscogee (Creek) Nation ("Plaintiff" or "Nation"), brings this First Amended Complaint for compensatory, punitive, and other damages, and restitution, disgorgement, and civil penalties. The Defendants are:

A. Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company; Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; Actavis LLC; Actavis Pharma, Inc.; Allergan Finance LLC; Watson Laboratories, Inc.; Teva Pharmaceuticals USA, Inc.; Amneal Pharmaceuticals, Inc.; and KVK-Tech, Inc. (collectively, "Marketing Manufacturer Defendants");

B. Amneal Pharmaceuticals, Inc. and KVK-Tech, Inc. (collectively, "Diversion Manufacturer Defendants");

C. McKesson Corporation, Cardinal Health, Inc.; Cardinal Health 110, LLC, AmerisourceBergen Corporation; AmerisourceBergen Drug Corporation; Morris & Dickson Co., LLC; Walgreens Boots Alliance, Inc.; Walgreen Co.; Wal-Mart Stores, Inc.; SAJ Distributors; GCP Pharma LLC; Anda Pharmaceuticals, Inc.; Anda, Inc.; Omnicare Distribution Center LLC; Smith Drug Company; The Harvard Drug Group, LLC; Pharmacy Buying Association; and H.D. Smith, LLC (collectively, "Distributor Defendants"); and

D. CVS Health Corporation; CVS Pharmacy, Inc.; Oklahoma CVS Pharmacy, LLC; Walgreens Boots Alliance, Inc.; Walgreen Co.; Wal-Mart Stores, Inc.; The Drug Warehouse; May's Drug Store; Reasor's LLC, Med-X Corporation; Economy Discount Pharmacy; Economy Pharmacy, Inc.; Economy Pharmacy Express; City Drug Co., City Drug of Coweta, Inc.; Spoon Drugs, Inc.; Carefirst Pharmacy, Inc.; Cityplex Pharmacy; Couch Pharmacy on Sheridan; Ernie's Pharmacy & Wellness Center, Inc.; Freeland Brown Pharmacy, Inc.; Gaddy Discount Drug, Inc.; Getman-Apothecary Shoppe, Inc.; Langsam Health Services, LLC; M & D Star Drug, Inc.; Med-Econ Drug, Inc.; Olympia Pharmacy; Pippenger Pharmacies LLC; and Rogers Drug Co. Inc. (collectively, "Pharmacy Defendants").

Marketing Manufacturer Defendants, Diversion Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants are referred to collectively as "Defendants."

INTRODUCTION

1. Prescription opioids, which include both name-brand prescription opioids and their generic equivalents, are powerful pain-reducing medications. When used properly, they can help manage pain for certain patients. But, even then, these drugs can cause addiction,

overdose, and death. When used to treat chronic pain, or when used for non-medical purposes, those risks are amplified.

2. In recent years, opioid use for both chronic pain and non-medical purposes has grown dramatically, resulting in an epidemic of abuse. Nationwide, millions of Americans are addicted to prescription opioids, and tens of thousands die annually from opioid overdoses. According to the Centers for Disease Control and Prevention ("CDC"), in Oklahoma, where the Nation is located, 2,315 people died of drug overdoses between 2014 and 2016, and the "main driver" of these deaths were prescription and illicit opioids.[1]

3. Defendants' conduct caused this epidemic.

4. Marketing Manufacturer Defendants have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids. Although manufacturers are prohibited from marketing opioids through misstatements or omissions of material facts, Marketing Manufacturer Defendants did so through this campaign, which includes websites, promotional materials, conferences, guidelines for doctors, and other vehicles.

5. This aggressive marketing campaign enabled Marketing Manufacturer Defendants to overcome the longstanding medical consensus that opioids were unsafe for the treatment of

[1] CDC, *Drug Overdose Death Data*, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last updated December 19, 2017) (777 deaths in 2014; 725 deaths in 2015; 813 deaths in 2016).

chronic pain, and between 1999 and 2016, the number of opioids prescribed nationwide quadrupled,[2] as did deaths from prescription opioids.[3]

6. The increase in opioid prescriptions to treat chronic pain in turn led to a massive increase in the number of people seeking prescription opioids for non-medical uses and becoming addicted. Nationally, the number of people who take prescription opioids for non-medical purposes is now greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.[4] In Oklahoma alone, data from the Substance Abuse and Mental Health Services Administration indicate that over 194,000 residents use prescription opioids for non-medical purposes.[5]

7. Oklahoma, where the vast majority of the Nation's citizens reside, leads the country in opioid abuse. In recent years, it has ranked number one nationally for the non-medical use of prescription opioids for adults.[6] In recent years, more overdose deaths in

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[2] Li Hui Chen et al., *Drug-Poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr. for Health Statistics Data Brief (Sept. 2014), https://www.cdc.gov/nchs/data/databriefs/db166.pdf; Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity and Mortality Weekly Report 1445 (Dec. 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[3] Anna Lembke, *Drug Dealer MD: How Doctors Were Duped, Patients Got Hooked, and Why It's Hard to Stop* 4 (2016).

[4] Substance Abuse and Mental Health Servs. Admin., *Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings*, NSDUH Series H-38A, HHS Publication No. SMA 10-4586 Findings (2010).

[5] Substance Abuse and Mental Health Servs. Admin., *National Survey on Drug Use and Health: Comparison of 2002–2003 and 2013–2014 Population Percentages (50 States and the District of Columbia)* 16–17 (2015), http://www.samhsa.gov/data/sites/default/files/NSDUHsaeLongTermCHG2014/NSDUHsaeLongTermCHG2014.pdf.

[6] Rachel N. Lipari et al., Substance Abuse and Mental Health Servs. Admin., *State and Substate Estimates of Nonmedical Use of Prescription Pain Relievers* (2017), https://www.samhsa.gov/data/sites/default/files/report_3187/ShortReport-3187.html.

Oklahoma involved hydrocodone or oxycodone than alcohol, cocaine, methamphetamine, heroin, and all other illegal drugs combined.[7] Deaths of Nation citizens contribute to these statewide statistics, and the Nation has suffered injury different in kind than the general public.

8. This increase in non-medical demand and addiction has led to an increase in diversion, which occurs when the supply chain of prescription opioids is broken and drugs are transferred from a legitimate channel to an illegitimate one.

9. The legitimate supply chain for prescription opioids begins with the manufacture and packaging of the pills. Manufacturers (including Diversion Manufacturer Defendants) then transfer the pills to distributors—in particular Distributor Defendants, who, upon information and belief, together account for at least 85% of opioid shipments in the United States. Distributors (including Distributor Defendants) then supply opioids to pharmacies (including Pharmacy Defendants) and others who dispense the drugs to consumers.

10. At the manufacturer level, diversion occurs whenever opioid manufacturers fill suspicious orders from distributors. As discussed below, suspicious orders include orders of an unusually large size, orders of a size that are disproportionately large in comparison to the population of a community, orders that deviate from a normal pattern, and orders of unusual frequency. Diversion also occurs when manufacturers allow opioids to be lost or stolen from inventory or in transit.

11. At the distributor level, diversion occurs whenever opioid distributors fill suspicious orders from retailers such as pharmacies. As discussed below, suspicious orders include orders of an unusually large size, orders of a size that are disproportionately large in

[7] *See* CDC, Wide-ranging Online Data for Epidemiologic Research (WONDER), http://wonder.cdc.gov.

comparison to the population of a community served by a pharmacy, orders that deviate from a normal pattern, and orders of unusual frequency. Diversion also occurs when distributors allow opioids to be lost or stolen from inventory or in transit.

12. At the pharmacy level, diversion occurs when a pharmacist fills a prescription despite having reason to believe it has no legitimate medical purpose. A prescription may lack such a purpose when a patient is a drug dealer or opioid-dependent, seeks to fill multiple prescriptions from different pharmacies or obtain prescriptions from multiple providers, travels great distances between a doctor and a pharmacy to fill a prescription, presents multiple prescriptions for the largest dose of more than one controlled substance such as opioids and benzodiazepines, or when there are other "red flags." Opioids are also diverted from pharmacies when they are stolen by employees or others, obtained with stolen, forged, or invalid prescriptions, or sold without prescriptions.

13. Studies suggest that a substantial number of the opioid prescriptions issued in Oklahoma each year are diverted to non-medical uses. These conclusions about the extent of prescription opioid diversion are further supported by Drug Enforcement Administration ("DEA") data showing that in the past few years, Oklahoma, where the Nation is located, has seen annual distribution exceeding 660 milligrams per citizen,[8] and 5,923 milligrams per opioid user.[9]

[8] Drug Enf't Admin., ARCOS 3 – Report 1, *Retail Drug Distribution By Zip Code Within State by Grams Weight*,
https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2013/2013_rpt1.pdf;
https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2014/2014_rpt1.pdf;
https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2015/2015_rpt1.pdf;
https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/report_yr_2016.pdf.

[9] Wenjun Zhong et al., *Age and Sex Patterns of Drug Prescribing in a Defined American Population*, 7 Mayo Clinic Proceedings 697, 700 (2013).

14. As detailed below, Diversion Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants (collectively, "Diversion Defendants") have legal obligations to combat diversion. Diversion Defendants have routinely and continuously violated these obligations, and instead have taken advantage of the massively increased demand for prescription opioids for non-medical uses by profiting heavily from the sale of opioids that they knew or should have known were being diverted from the legitimate supply chain to illegitimate channels of distribution. The failure of Diversion Defendants to comply with their legal obligations to prevent diversion and to alert authorities to potential diversion continues today, despite (a) the well-known harm resulting from the opioid crisis, and (b) substantial fines for diversion levied against multiple of the Diversion Defendants.

15. The misconduct of Defendants, including their consistent failure to comply with their legal obligations and their concealment thereof, has led to an epidemic of prescription opioid abuse. American Indians, including the Nation, have been significantly impacted by this epidemic. American Indians suffer the highest per capita rate of opioid overdoses.[10]

16. Hundreds of American Indians have died of opioid overdoses in recent years. And for every opioid overdose death, it is estimated that there are 10 treatment admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825 non-medical users of opioids.[11]

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

[11] Jennifer DuPuis, *The Opioid Crisis in Indian Country*, at 37, https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf (last visited Feb. 5, 2018); Gery P. Guy, Jr. et al., *Emergency Department Visits Involving Opioid Overdoses, U.S., 2010–2014*, 54 Am. J. of Preventive Medicine (Jan. 2018), http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext.

17. The impact on American Indian children is particularly devastating. The CDC has reported that approximately one out of every 14.5 American Indian youths aged 12 or older used prescription opioids for non-medical purposes in 2012. This is 60% higher than the rate for white youths. Similarly, it has been reported that by twelfth grade, nearly 13% of American Indian teens have used OxyContin, an opioid manufactured by Defendant Purdue Pharma L.P.[12] The fact that American Indian teens are easily able to obtain OxyContin at these alarming rates indicates the degree to which drug diversion has created an illegal secondary market for opioids.

18. The opioid epidemic resulting from Defendants' conduct has injured even the youngest members of Indian tribes. In 1992, in the United States, only 2% of pregnant women admitted for drug treatment services abused opioids. By 2012, opioids accounted for 38% of all drug treatment admissions of pregnant women.[13] 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, which can have adverse short- and long-term developmental consequences.[14]

19. Pregnant American Indian women are up to 8.7 times more likely than pregnant women from other groups to be diagnosed with opioid dependency or abuse, and in some communities more than one in 10 pregnant American Indian women have a diagnosis of opioid dependency or abuse.[15] On information and belief, the same is true of women in the Nation.

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[12] Linda R. Stanley, *Rates of Substance Use of American Indian Students in 8th, 10th, and 12th Grades Living on or Near Reservations: Update, 2009–2012*, Pub. Health Rep. (Mar.–Apr. 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904895/table/T1/.
[13] Naana Afua Jumah, *Rural, Pregnant, and Opioid Dependent: A Systematic Review*, 10 Substance Abuse 35 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/.
[14] Jean Y. Ko et al., *CDC Grand Rounds: Public Health Strategies to Prevent Neonatal Abstinence Syndrome*, 66 Morbidity and Mortality Weekly Report 242 (Mar. 10, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf.
[15] DuPuis, *supra* note 9, at 64.

20. Diversion Defendants' prescription opioid diversion on and around the Nation contributes to a range of social problems. Adverse impacts on the Nation's families include child abuse and neglect, and family dysfunction. Nation children are regularly removed from their families as a result of prescription opioid dependency and abuse by both children and parents. These removals harm Nation children and families, and they harm the Nation itself, particularly when children are placed with families outside the Nation.

21. Other social problems caused by the opioid epidemic include criminal behavior, poverty, property damage, unemployment, and social despair. As a result of these adverse social outcomes, more and more Nation resources are devoted to addiction-related problems, leaving a diminished pool of resources available for education, cultural preservation, and social programs. Meanwhile, the opioid crisis diminishes the Nation's available workforce, decreases productivity, increases poverty, and consequently requires greater expenditures for governmental assistance.

22. Damages suffered by the Nation include the costs of (a) medical care, therapeutic and prescription drugs, and other treatments for patients suffering from opioid-related addiction, overdoses, or disease; (b) law enforcement and public safety measures necessitated by the opioid crisis; (c) opioid-related counseling and rehabilitation services; (d) welfare for children whose parents suffer from opioid-related disease or incapacitation; (e) increased crime, property damage, and public blight caused by opioids; and (f) lost productivity of its citizens and businesses.

23. To remedy all Defendants' misconduct, the Nation brings this action for: (a) violations of the Racketeer-Influenced and Corrupt Organizations Act ("RICO");

(b) violations of the Lanham Act; (c) common law nuisance; (d) negligence; (e) unjust enrichment; and (f) civil conspiracy.

24. The Nation seeks: (a) injunctive relief; (b) compensatory damages; (c) statutory damages and penalties pursuant to Federal and applicable state law; (d) reimbursement of all payments fraudulently induced by all Defendants' conduct; (e) disgorgement of all amounts unjustly obtained by all Defendants; (f) restitution of all expenditures by the Nation resulting from all Defendants' conduct; (g) punitive damages; (h) attorneys' fees and costs; and (i) such further relief as justice may require.

PARTIES

I. PLAINTIFF

25. The Nation is a federally recognized Indian tribe with a membership of 83,570 citizens. It covers 4,867 square miles that lie within the state of Oklahoma. It exercises sovereign governmental authority within its territory and over its citizens.

26. The Nation provides healthcare to its members and other Native Americans in the region pursuant to a compact under the Indian Self Determination and Education Assistance Act.[16]

27. The Nation, by and through counsel, including Kevin Dellinger, Attorney General of the Nation, brings this action in its proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of the citizens of the Nation to stop the opioid epidemic within the Nation and to recover damages and seek other redress from harm caused by Defendants' improper marketing, sales, distribution, dispensing, and reporting practices related to prescription opioids.

[16] 25 U.S.C. §§ 5301–5423.

II. DEFENDANTS

A. Marketing Manufacturer Defendants

28. Defendant Purdue Pharma L.P. (together with Purdue Pharma Inc. and The Purdue Frederick Company, "Purdue") is a Delaware business entity with its principal place of business in Connecticut. During all relevant times, Purdue Pharma L.P. has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

29. Defendant Purdue Pharma Inc. (together with Purdue Pharma L.P. and The Purdue Frederick Company, "Purdue") is a New York business entity with its principal place of business in Connecticut. During all relevant times, Purdue Pharma Inc. has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

30. Defendant The Purdue Frederick Company (together with Purdue Pharma L.P. and Purdue Pharma Inc., "Purdue") is a Delaware business entity with its principal place of business in Connecticut. At all relevant times, The Purdue Frederick Company has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

31. Defendant Endo Health Solutions Inc. (together with Endo Pharmaceuticals Inc., "Endo") is a Delaware business entity with its principal place of business in Pennsylvania. At all relevant times, Endo Health Solutions Inc. has manufactured and distributed substantial amounts of name-brand prescription opioids and their generic equivalents that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

32. Defendant Endo Pharmaceuticals Inc. (together with Endo Health Solutions Inc., "Endo") is a Delaware business entity with its principal place of business in Pennsylvania. At all relevant times, Endo Pharmaceuticals Inc. has manufactured and distributed substantial amounts of name-brand prescription opioids and their generic equivalents that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

33. Defendant Actavis LLC (together with Actavis Pharma, Inc., Allergan Finance LLC, and Watson Laboratories, Inc., "Actavis/Allergan") is a Delaware business entity with its principal place of business in New Jersey. At all relevant times, Actavis/Allergan has manufactured and distributed substantial amounts of name-brand prescription opioids and their generic equivalents that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

34. Defendant Actavis Pharma, Inc. (together with Actavis LLC, Allergan Finance LLC, and Watson Laboratories, Inc., "Actavis/Allergan") is a Delaware business entity with its principal place of business in New Jersey. At all relevant times, Actavis/Allergan has manufactured and distributed substantial amounts of name-brand prescription opioids and their generic equivalents that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

35. Defendant Allergan Finance LLC (together with Actavis LLC, Actavis Pharma, Inc., and Watson Laboratories, Inc., "Actavis/Allergan") is a Nevada business entity with its principal place of business in New Jersey. At all relevant times, Actavis/Allergan has manufactured and distributed substantial amounts of name-brand prescription opioids and their generic equivalents that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

36. Defendant Watson Laboratories, Inc. (together with Actavis LLC, Actavis Pharma, Inc., and Allergan Finance LLC, "Actavis/Allergan") is a Nevada business entity with its principal place of business in California. At all relevant times, Actavis/Allergan has manufactured and distributed substantial amounts of name-brand prescription opioids and their generic equivalents that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

37. Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware business entity with its principal place of business in Pennsylvania. At all relevant times, Teva has manufactured and distributed substantial amounts of name-brand prescription opioids and their generic equivalents that have been and continue to be sold nationwide, including in Oklahoma, where the Nation is located.

38. Defendant Amneal Pharmaceuticals, Inc. ("Amneal") is a Delaware business entity with its principal place of business in New Jersey. Amneal is authorized to conduct business in Oklahoma. At all relevant times, Amneal has sold nationwide, including in Oklahoma, where the Nation is located.

39. Defendant KVK-Tech, Inc. ("KVK") is a Pennsylvania business entity with its principal place of business in Pennsylvania. KVK is authorized to conduct business in Oklahoma. At all relevant times, KVK has sold nationwide, including in Oklahoma, where the Nation is located.

40. As discussed further below, in violation of their legal obligations, each Marketing Manufacturer Defendant has made misstatements or omitted information regarding the risks of using prescription opioids to treat chronic pain.

B. Diversion Manufacturer Defendants

41. Defendant Amneal is a Delaware business entity with its principal place of business in New Jersey. Amneal is authorized to conduct business in Oklahoma. At all relevant times, Amneal has sold and distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

42. Defendant KVK is a Pennsylvania business entity with its principal place of business in Pennsylvania. KVK is authorized to conduct business in Oklahoma. At all relevant times, KVK has sold and distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

43. As discussed below, each Diversion Manufacturer Defendant has consistently failed to comply with its legal obligations concerning prescription opioid diversion.

C. Distributor Defendants

44. Defendant McKesson Corporation ("McKesson") is a Delaware business entity with its principal place of business in California. McKesson is authorized to conduct business in Oklahoma. At all relevant times, McKesson has distributed substantial amounts of prescription opioids in Oklahoma and the Nation.

45. Defendant Cardinal Health, Inc. (together with Cardinal Health 110, LLC, "Cardinal") is an Ohio business entity with its principal place of business in Ohio. Cardinal is authorized to conduct business in Oklahoma. At all relevant times, Cardinal has distributed substantial amounts of prescription opioids in Oklahoma and the Nation.

46. Defendant Cardinal Health 110, LLC (together with Cardinal Health, Inc., "Cardinal") is a Delaware business entity with its principal place of business in Ohio. Cardinal

is authorized to conduct business in Oklahoma. At all relevant times, Cardinal has distributed substantial amounts of prescription opioids in Oklahoma and the Nation.

47. Defendant AmerisourceBergen Corporation (together with AmerisourceBergen Drug Corporation, "AmerisourceBergen") is a Delaware business entity with its principal place of business in Pennsylvania. AmerisourceBergen is authorized to conduct business in Oklahoma. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids in Oklahoma and the Nation.

48. Defendant AmerisourceBergen Drug Corporation (together with AmerisourceBergen Corporation, "AmerisourceBergen") is a Delaware business entity with its principal place of business in Pennsylvania. AmerisourceBergen is authorized to conduct business in Oklahoma. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids in Oklahoma and the Nation.

49. Defendant Morris & Dickson Co., LLC ("Morris & Dickson") is a Louisiana business entity with its principal place of business in Louisiana. Morris & Dickson is authorized to conduct business in Oklahoma. At all relevant times, Morris & Dickson has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

50. Defendant Walgreens Boots Alliance, Inc. (together with Walgreen Co., "Walgreens") is a Delaware business entity with its principal place of business in Illinois. Walgreens is authorized to conduct business in Oklahoma. At all relevant times, Walgreens has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

51. Defendant Walgreen Co. (together with Walgreens Boots Alliance, Inc., "Walgreens") is an Illinois business entity with its principal place of business in Illinois.

Walgreens is authorized to conduct business in Oklahoma. At all relevant times, Walgreens has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

52. Defendant Wal-Mart Stores, Inc. ("Walmart") is a Delaware business entity with its principal place of business in Arkansas. At all relevant times, Walmart has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

53. Defendant SAJ Distributors ("SAJ") is an Arkansas business entity with its principal place of business in Arkansas. At all relevant times, SAJ has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

54. Defendant GCP Pharma LLC ("GCP") is an Oklahoma business entity with its principal place of business in Oklahoma. At all relevant times, GCP has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

55. Defendant Anda Pharmaceuticals, Inc. (with Anda, Inc., "Anda") is a Florida business entity with its principal place of business in Mississippi. At all relevant times, Anda has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

56. Defendant Anda, Inc. (together with Anda Pharmaceuticals, Inc., "Anda") is a Florida business entity with its principal place of business in Florida. At all relevant times, Anda has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

57. Defendant Omnicare Distribution Center LLC ("Omnicare") is a Delaware business entity with its principal place of business in Ohio. At all relevant times, Omnicare has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

58. Defendant Smith Drug Company ("Smith") is a South Carolina business entity with its principal place of business in South Carolina. At all relevant times, Smith has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

59. Defendant The Harvard Drug Group, LLC ("Harvard") is a Michigan business entity with its principal place of business in Michigan. At all relevant times, Harvard has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

60. Defendant Pharmacy Buying Association ("PBA") is a Missouri business entity with its principal place of business in Missouri. At all relevant times, PBA has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

61. Defendant H.D. Smith, LLC ("H.D. Smith") is a Delaware business entity with its principal place of business in Illinois. At all relevant times, H.D. Smith has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.

62. As discussed below, each Distributor Defendant has consistently failed to comply with its legal obligations concerning prescription opioid diversion. Additionally, McKesson, Cardinal, AmerisourceBergen, Walgreens, and Walmart have paid civil penalties to resolve government allegations regarding prescription opioid diversion.

D. Pharmacy Defendants

63. Defendant CVS Health Corporation (together with CVS Pharmacy, Inc. and Oklahoma CVS Pharmacy, LLC, "CVS") is a Delaware business entity with its principal place of business in Rhode Island. CVS is authorized to conduct business in Oklahoma. At all relevant times, CVS has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

64. Defendant CVS Pharmacy, Inc. (together with CVS Health Corporation and Oklahoma CVS Pharmacy, LLC, "CVS") is a Rhode Island business entity with its principal place of business in Rhode Island. CVS is authorized to conduct business in Oklahoma. At all relevant times, CVS has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

65. Defendant Oklahoma CVS Pharmacy, LLC (together with CVS Health Corporation and CVS Pharmacy, Inc., "CVS") is an Oklahoma business entity with its principal place of business in Rhode Island. CVS is authorized to conduct business in Oklahoma. At all relevant times, CVS has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

66. Defendant Walgreens Boots Alliance, Inc. (together with Walgreen Co., "Walgreens") is a Delaware business entity with its principal place of business in Illinois. Walgreens/Boots is authorized to conduct business in Oklahoma. At all relevant times, Walgreens/Boots has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

67. Defendant Walgreen Co. (together with Walgreens Boots Alliance, Inc., "Walgreens") is an Illinois business entity with its principal place of business in Illinois. Walgreen Co. is authorized to conduct business in Oklahoma. At all relevant times, Walgreen Co. has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation

citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

68. Defendant Walmart is a Delaware business entity with its principal place of business in Arkansas. At all relevant times, Walmart has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

69. Defendant The Drug Warehouse ("Drug Warehouse") is an Oklahoma business entity with its principal place of business in Oklahoma. Drug Warehouse is authorized to conduct business in Oklahoma. At all relevant times, Drug Warehouse has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

70. Defendant May's Drug Store ("May's") is an Oklahoma business entity with its principal place of business in Oklahoma. May's is authorized to conduct business in Oklahoma. At all relevant times, May's has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

71. Defendant Reasor's LLC ("Reasor's") is an Oklahoma business entity with its principal place of business in Oklahoma. Reasor's is authorized to conduct business in Oklahoma. At all relevant times, Reasor's has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation

hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

72. Defendant Med-X Corporation is an Oklahoma business entity with its principal place of business in Oklahoma. Med-X is authorized to conduct business in Oklahoma. At all relevant times, Med-X has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

73. Defendant Economy Discount Pharmacy (together with Economy Pharmacy, Inc. and Economy Pharmacy Express, "Economy") is a Georgia business entity with its principal place of business in Georgia. Economy is authorized to conduct business in Oklahoma. At all relevant times, Economy has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

74. Defendant Economy Pharmacy, Inc. (together with Economy Discount Pharmacy and Economy Pharmacy Express, "Economy") is an Oklahoma business entity with its principal place of business in Oklahoma. Economy is authorized to conduct business in Oklahoma. At all relevant times, Economy has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

75. Defendant Economy Pharmacy Express (together with Economy Discount Pharmacy and Economy Pharmacy, Inc., "Economy") is an Oklahoma business entity with its principal place of business in Oklahoma. Economy is authorized to conduct business in Oklahoma. At all relevant times, Economy has sold and continues to sell prescription opioids at

locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

76. Defendant City Drug Co. (together with City Drug of Coweta, "City Drug") is a Tennessee business entity with its principal place of business in Tennessee. City Drug is authorized to conduct business in Oklahoma. At all relevant times, City Drug has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

77. Defendant City Drug of Coweta, Inc. (together with City Drug Co., "City Drug") is an Oklahoma business entity with its principal place of business in Oklahoma. City Drug is authorized to conduct business in Oklahoma. At all relevant times, City Drug has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

78. Defendant Spoon Drugs, Inc. ("Spoon") is an Oklahoma business entity with its principal place of business in Oklahoma. Spoon is authorized to conduct business in Oklahoma. At all relevant times, Spoon has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

79. Defendant Carefirst Pharmacy, Inc. ("Carefirst") is an Oklahoma business entity with its principal place of business in Oklahoma. Carefirst is authorized to conduct business in Oklahoma. At all relevant times, Carefirst has sold and continues to sell prescription opioids at

locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

80. Defendant Cityplex Pharmacy ("Cityplex") is an Oklahoma business entity with its principal place of business in Oklahoma. Cityplex is authorized to conduct business in Oklahoma. At all relevant times, Cityplex has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

81. Defendant Couch Pharmacy on Sheridan ("Couch") is an Oklahoma business entity with its principal place of business in Oklahoma. Couch is authorized to conduct business in Oklahoma. At all relevant times, Couch has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

82. Defendant Ernie's Pharmacy & Wellness Center, Inc. ("Ernie's") is an Oklahoma business entity with its principal place of business in Oklahoma. Ernie's is authorized to conduct business in Oklahoma. At all relevant times, Ernie's has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

83. Defendant Freeland Brown Pharmacy, Inc. ("Freeland") is an Oklahoma business entity with its principal place of business in Oklahoma. Freeland is authorized to conduct

business in Oklahoma. At all relevant times, Freeland has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

84. Defendant Gaddy Discount Drug, Inc. ("Gaddy") is an Oklahoma business entity with its principal place of business in Oklahoma. Gaddy is authorized to conduct business in Oklahoma. At all relevant times, Gaddy has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

85. Defendant Getman-Apothecary Shoppe, Inc. ("Getman") is an Oklahoma business entity with its principal place of business in Oklahoma. Getman is authorized to conduct business in Oklahoma. At all relevant times, Getman has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

86. Defendant Langsam Health Services, LLC ("Langsam") is a Delaware business entity with its principal place of business in Ohio. Langsam is authorized to conduct business in Oklahoma. At all relevant times, Langsam has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

87. Defendant M & D Star Drug, Inc. ("M&D") is an Oklahoma business entity with its principal place of business in Oklahoma. M&D is authorized to conduct business in Oklahoma. At all relevant times, M&D has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

88. Defendant Med-Econ Drug, Inc. ("Med-Econ") is an Oklahoma business entity with its principal place of business in Oklahoma. Med-Econ is authorized to conduct business in Oklahoma. At all relevant times, Med-Econ has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

89. Defendant Olympia Pharmacy ("Olympia") is an Oklahoma business entity with its principal place of business in Oklahoma. Olympia is authorized to conduct business in Oklahoma. At all relevant times, Olympia has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

90. Defendant Pippenger Pharmacies LLC ("Pippenger") is an Oklahoma business entity with its principal place of business in Oklahoma. Pippenger is authorized to conduct business in Oklahoma. At all relevant times, Pippenger has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close

proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

91. Defendant Rogers Drug Co. Inc. ("Rogers") is an Oklahoma business entity with its principal place of business in Oklahoma. Rogers is authorized to conduct business in Oklahoma. At all relevant times, Rogers has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation's healthcare system.

92. As discussed below, each Pharmacy Defendant has consistently failed to comply with its legal obligations concerning prescription opioid diversion. Additionally, each Pharmacy Defendant has paid civil penalties to resolve government allegations regarding prescription opioid diversion.

JURISDICTION AND VENUE

93. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1362 because this action is brought by an Indian tribe and presents a federal question. This Court has supplemental jurisdiction over the state-law causes of action under 28 U.S.C. § 1367 because the state-law claims are part of the same case or controversy.

94. This Court has personal jurisdiction over all Defendants because each Defendant has substantial contacts and business relationships with Oklahoma, including consenting to be sued in Oklahoma by registering an agent for service of process and/or obtaining a distributor license, and has purposefully availed itself of business opportunities in Oklahoma, including by marketing, distributing, or selling prescription opioids in Oklahoma and on and around the Nation.

95. Venue is proper in this Court under 28 U.S.C. § 1391(b) 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 jurisdiction.

FACTUAL BACKGROUND

I. PRESCRIPTION OPIOIDS ARE HIGHLY DANGEROUS

96. Prescription opioids are powerful pain-reducing medications that include non-synthetic, partially-synthetic, and fully-synthetic derivatives of the opium poppy. While these drugs can have benefits when used properly, they also pose serious risks. In particular, they present "substantially increase[d]" risk when used to treat chronic pain and "can cause serious harm, including addiction, overdose and death" when "misused or abused."[17]

97. Given these risks, the marketing, distribution, and sale of prescription opioids are heavily regulated by Federal law, including the Federal Controlled Substances Act ("FCSA"), 21 U.S.C. §§ 801 *et seq.*, and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S. §§ 321 *et seq.* Similarly, numerous state regulations, including numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances, impose strict controls and requirements throughout the prescription opioid distribution chain.

98. As discussed below, despite the dangers of prescription opioids, Marketing Manufacturer Defendants wrongfully marketed them through misleading statements that minimized the risks of these drugs and failed to disclose accurately the true magnitude of those risks. The actions of Marketing Manufacturer Defendants created a huge market for prescription opioids, which in turn led to massive diversion of these drugs from legitimate to illegitimate

[17] Food and Drug Admin., *Opioid Medications*, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm (last updated Feb. 15, 2018).

channels. Diversion Defendants, who have duties to implement effective measures to prevent diversion, wrongfully turned a blind eye to it. Defendants as a group also concealed their wrongdoing from the public and the Nation. As a result of all Defendants' wrongful acts, the Nation and its citizens have suffered injuries and damages.

II. MARKETING MANUFACTURER DEFENDANTS HAVE LEGAL DUTIES TO DISCLOSE ACCURATELY THE RISKS OF OPIOIDS

99. Each Marketing Manufacturer Defendant has a duty under Federal and Oklahoma law to exercise reasonable care in marketing and selling opioids.

100. The FDCA prohibits "the introduction . . . into interstate commerce of any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a). "Misbranding" includes misleading advertising. 21 U.S.C. § 352. Misleading advertising, in turn, includes both "representations made or suggested by statement, word, design, device, or any combination thereof," and

> the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C. § 331(n).

101. Marketing Manufacturer Defendants also have a common law duty to make a full and fair disclosure as to the matters about which they choose to speak.

III. MARKETING MANUFACTURER DEFENDANTS VIOLATED THEIR DUTIES

A. Marketing Manufacturer Defendants Made Misleading Statements About the Risks of Prescribing Opioids to Treat Chronic Pain and Failed to State Accurately the Magnitude of Those Risks

102. Marketing Manufacturer Defendants have engaged in a multi-million dollar marketing campaign to minimize and misstate the risks of addiction and abuse when prescription opioids are used to treat chronic pain.

103. Marketing Manufacturer Defendants made statements through websites, promotional materials, conferences, guidelines for doctors, and other vehicles that suggested that the risk of addiction when opioids are used for chronic pain was low—statements directly contrary to established scientific evidence. Marketing Manufacturer Defendants' marketing claims also differ from the safety warnings that Marketing Manufacturer Defendants must place on many of their opioid products. In fact, as discussed further below, Marketing Manufacturer Defendants have been repeatedly fined or otherwise sanctioned for their misleading statements in the marketing of opioids.

1. Marketing Manufacturer Defendants Misrepresented the Risks of Addiction to Prescription Opioids

104. The Marketing Manufacturer Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids, including (1) front groups that appeared to be independent from Marketing Manufacturer Defendants ("Front Groups"), and (2) so-called "Key Opinion Leaders" ("KOLs"), that is, doctors who were paid by the Marketing Manufacturer Defendants to promote their pro-opioid message. The Front Groups put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and

understated their risks.[18] Marketing Manufacturer Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies. The American Pain Foundation, the American Academy of Pain Medication, the American Pain Society, the Federation of State Medical Boards, the Alliance for Patient Access, the U.S. Pain Foundation, and the American Geriatrics Society all functioned as Front Groups.

105. Acting through Front Groups, which were nominally independent, neutral organizations, Marketing Manufacturer Defendants contributed content to numerous "guidelines" on opioid use. These guidelines misleadingly downplayed the risks of addiction when opioids are prescribed for chronic pain. For instance, an October 2011 pamphlet entitled, "A Policymaker's Guide to Understanding Pain & Its Management," put out by a Front Group called the American Pain Foundation and "made possible by support from Purdue Pharma LP," asserted that "[l]ess than 1 percent of children treated with opioids become addicted" and that pain was generally "undertreated" due to "misconceptions about opioid addiction."[19] Similarly, "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain," a February 2009 article funded by the American Pain Society, another Front Group, and written by several authors with financial ties to Marketing Manufacturer Defendants, promoted opioids as "safe and effective" for chronic pain treatment and indicated that the risk of addiction

[18] Staff of S. Comm. on Homeland Sec. & Governmental Affairs, 115th Cong., *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Comm. Print 2018), www.hsdl.org/?abstract&did=808171, at 3.
[19] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

was manageable for all patients regardless of past drug abuse history.[20] Likewise, "Treatment Options: A Guide for People Living with Pain," a 2006 American Pain Foundation pamphlet financially supported by Purdue, claimed that addiction is rare and limited to certain extreme cases.[21] Endo also sponsored the American Pain Foundation; in 2010 alone, the organization received more than $2,500,000 from Endo.[22] By asserting that the Front Groups were independent non-profit organizations with missions other than the increase of opioid use, the Marketing Manufacturer Defendants and Front Groups concealed that the Front Groups were acting under the practical control of, and/or for the benefit of, the Marketing Manufacturer Defendants and the creation of an increased market for opioids that would yield higher revenue and profits.

106. Marketing Manufacturer Defendants produced and provided directly to doctors and patients marketing materials that made similar misstatements. Purdue issued marketing materials, starting in 1996, stating that "addiction to opioids legitimately used in the management of pain is very rare."[23] Endo distributed a pamphlet, "Living with Someone with Chronic Pain," which stated that most healthcare providers agree that most people do not develop an addiction.

107. Marketing Manufacturer Defendants ran websites that promoted similar misleading claims. For example, Endo sponsored painknowledge.com and painaction.com,

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[20] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 The J. of Pain 113 (Feb. 2009), http://dx.doi.org/10.1016/j.jpain.2008.10.008.

[21] Am. Pain Found., *Treatment Options: A Guide for People Living with Pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[22] Am. Pain Found., *2010 Annual Report* (Dec. 20, 2011), https://archive.org/details/277604-apf-2010-annual-report.

[23] Drug Label for Oxycodone Hydrochloride 5mg Capsule, https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=41068.

which claimed, as of 2009 and 2015, respectively, that "[p]eople who take opioids as prescribed usually do not become addicted" and that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them."[24]

108. Endo also represented that "[t]aking opioids for pain relief is not addiction" and that "[a]ddiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problem."[25] In the same publication, Endo suggested that patients use the following test to determine whether they are addicted to opioids: "Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve pain and improve your function. You are not addicted."[26]

109. Marketing Manufacturer Defendants trained salesmen to downplay the risk of addiction. For instance, Purdue salesmen were instructed to tell doctors that opioids' addiction risk was "less than one percent."[27]

110. Marketing Manufacturer Defendants sponsored training sessions where doctors were given similar misleading information regarding the risks of opioid addiction. For example,

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[24] National Initiative on Pain Control, *Pain: Opioid Therapy* (2009), [https://web.archive.org/web/20101007083722/http://painknowledge.org/patiented/pdf/B697_%20Patient%20Handout_FINAL.pdf]; Joanne Zeis, *Opioid Medication and Addiction* (Aug. 17, 2017), https://www.painaction.com/opioid-medication-addiction/, at 4.
[25] Endo Pharmaceuticals, *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004), https://perma.cc/QN86-62PK.
[26] *Id.*
[27] U.S. Gov't Accountability Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/content-detail.html.

Purdue sponsored training sessions in the late 1990s and early 2000s where opioid addiction was described as "exquisitely rare."[28]

111. All of these statements were false. The CDC has stated that: (1) there is "extensive evidence" of the possible harms of opioids, including addiction; (2) "[o]pioid pain medication use presents serious risks," including addiction; and (3) using opioids to treat chronic pain "substantially increases" the risk of addiction.[29] Studies have found that up to 26% of long-term users of opioids experience problems with addiction or dependence.[30]

112. Moreover, in August 2016, the U.S. Surgeon General expressed concern that "heavy marketing to doctors" had led many to be "taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain," and noted the "devastating" results that followed from this misinformation.[31]

113. Findings by the Food and Drug Administration ("FDA") similarly belie Marketing Manufacturer Defendants' assertions that opioids are safe for treating chronic pain. These findings show that: (1) "most opioid drugs have 'high potential for abuse'"; (2) treatment of chronic pain with opioids poses "known serious risks," including "addiction, abuse, and misuse . . . overdose and death" even when used "at recommended doses"; and (3) opioids should be used only "in patients for whom alternative treatment options" have failed.[32] And

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[28] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 190 (2003).
[29] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
[30] *Id*.
[31] Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95-CUYC.
[32] Letter from Janet Woodcock, M.D., Dir. of Food and Drug Admin., Center for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wp-

several studies finding double-digit rates of prescription drug abuse in chronic pain patients controvert Marketing Manufacturer Defendants' claims that addiction rates are less than one percent.[33]

114. Similarly, a prominent neuropharmacologist at the Washington University School of Medicine in St. Louis, Dr. Theodore Cicero, remarked in 2016 that Purdue's OxyContin dosing is "the perfect recipe for addiction" due to its encouragement of psychological and physical withdrawal symptoms.[34]

115. As recently as June 2017, the New England Journal of Medicine published an analysis finding that Purdue's introduction of OxyContin into the marketplace coincided with a significant increase in misleading dissemination of the claim that addiction to opioids is rare. Moreover, this analysis concluded that "[w]e believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[35]

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content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

[33] Caleb J. Banta-Green et al., *Opioid Use Behaviors, Mental Health and Pain—Development of a Typology of Chronic Pain Patients*, 104 Drug and Alcohol Dependence 34 (Sept. 2009), http://dx.doi.org/10.1016/j.drugalcdep.2009.03.021; Joseph A. Boscarino et al., *Risk Factors for Drug Dependence Among Out-Patients on Opioid Therapy in a Large US Health-Care System*, 105 Addiction 1776 (Oct. 2010), http://dx.doi.org/10.1111/j.1360-0443.2010.03052.x; Jette Højsted et al., *Classification and Identification of Opioid Addiction in Chronic Pain Patients*, 14 European J. of Pain 1014 (Nov. 2010), http://dx.doi.org/10.1016/j.ejpain.2010.04.006.

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

[35] Pamela T. M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 New England J. of Med. 2194 (June 1, 2017), http://www.dx.doi.org/10.1056/NEJMc1700150.

2. Marketing Manufacturer Defendants Misleadingly Claimed that Patients Who Were Showing Signs of Addiction Were Not Actually Addicted

116. Marketing Manufacturer Defendants also made false statements that individuals showing signs of opioid addiction might instead have untreated pain requiring additional opioids—a baseless theory labeled "pseudoaddiction."

117. Purdue published a physician education pamphlet in 2011 suggesting that drug-seeking behavior could be a sign of "pseudoaddiction," which was described as "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." Purdue used the term "pseudoaddiction" in numerous other marketing materials, including one entitled "Responsible Opioid Prescribing – A Physician's Guide."[36] Endo also published materials promoting "pseudoaddiction."

118. However, there is no scientific support for the concept of "pseudoaddiction," a term coined by Dr. J. David Haddox, the Vice President of Health Policy for Purdue.[37] In fact, Endo's Vice President for Pharmacovigilance and Risk Management recently testified that he was not aware of any research validating the "'pseudoaddiction' concept."[38]

119. The 2016 CDC Guideline rejects the notion of pseudoaddiction. Instead of recommending that opioid dosages be increased if patients do not obtain relief, the guideline states that "[p]atients who do not experience clinically meaningful pain relief early in treatment .

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[36] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* (2007).
[37] Marion S. Greene & R. Andrew Chambers, *Pseudoaddiction: Fact or fiction? An Investigation of the Medical Literature*, 2 Current Addiction Reports 310 (Oct. 1, 2015), http://dx.doi.org/10.1007/s40429-015-0074-7.
[38] Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 7, *In re Endo Health Solutions Inc.*, No. 15-228 (Attorney General of the State of N.Y. 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

. . are unlikely to experience pain relief with longer term use"[39] and that doctors should "reassess[] pain and function within 1 month" so as to "minimize risks of long-term opioid use . . . ."[40]

3. Marketing Manufacturer Defendants Falsely Claimed There Was No Risk in Increasing Opioid Dosages to Treat Chronic Pain

120. Marketing Manufacturer Defendants also falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk.

121. Guidelines edited and sponsored by Purdue and Endo and put out by Front Groups[41]—namely "Treatment Options: A Guide for People Living with Pain" (2006) and "A Policymaker's Guide to Understanding Pain & Its Management" (2011)—claim that: (a) some patients "need" a larger opioid dosage, regardless of the dose prescribed; (b) opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain; and (c) dosage escalations, even unlimited ones, are "sometimes necessary."[42]

122. As recently as June 2015, Purdue's "In the Face of Pain" website was promoting the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, the patient should find another doctor who will. Also in 2015, Purdue presented a paper on the Problems of Drug Dependence, challenging the correlation between

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[39] Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1, 13 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
[40] *Id*. at 25.
[41] Am. Pain Found., *2010 Annual Report* (Dec. 20, 2011), https://archive.org/details/277604-apf-2010-annual-report.
[42] Am. Pain Found., *Treatment Options: A Guide for People Living with Pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf; Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

opioid dosage and overdose.[43] And in 2016, Purdue's Dr. Haddox falsely claimed that evidence does not show that Purdue's opioids are being abused in large numbers.[44] Dr. Haddox's false statements on behalf of Purdue are an example of active concealment of Purdue's wrongdoing with respect to causing the opioid epidemic.

123. Endo distributed a pamphlet in 2004, "Understanding Your Pain: Taking Oral Opioid Analgesics," which stated that patients "won't 'run out' of pain relief" so long as they increase dosages.[45] Endo also sponsored a website from 2004 to 2007, painknowledge.com, which claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain."

124. Marketing Manufacturer Defendants made these statements despite strong contrary scientific evidence. The FDA has stated that the available data "suggest a relationship between increasing opioid dosages and risk of certain adverse events."[46] The CDC has stated that there is "an established body of scientific evidence showing that overdose risk is increased at

[43] A. DeVeaugh-Geiss et al., *Is Opioid Dose a Strong Predictor of the Risk of Opioid Overdose?: Important Confounding Factors That Change the Dose–Overdose Relationship*, CPDD 76th Annual Scientific Meeting Program (June 2014), http://cpdd.org/wp-content/uploads/2016/07/2014CPDDprogrambook.pdf.

[44] Harrison Jacobs, *There is a Big Problem with the Government's Plan to Stop the Drug-Overdose Epidemic*, Business Insider, Mar. 14, 2016, http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3.

[45] Endo Pharmaceuticals, *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004), https://perma.cc/QN86-62PK.

[46] Letter from Janet Woodcock, M.D., Dir. of Food and Drug Admin., Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

higher opioid dosages," and has specifically recommended that doctors "avoid increasing doses" above 90 morphine milligram equivalents ("MME") per day. [47]

125. Nonetheless, Marketing Manufacturer Defendants misrepresented the effects of escalating dosages to further their relentless pursuit of corporate profit. The ability to escalate dosages was critical to Marketing Manufacturer Defendants' efforts to market opioids for chronic pain treatment because doctors would otherwise abandon treatment when patients built up tolerance and no longer obtained pain relief. And for at least some products, escalation of dosage was key: of the seven available OxyContin tablet strengths, the three strongest—40 milligrams (120 MME), 60 milligrams (180 MME), and 80 milligrams (240 MME)—all exceed the CDC limit when taken twice per day as directed. The Marketing Manufacturer Defendants' misrepresentations were made not only to keep the wrongfully created opioid epidemic going, but also to conceal the Marketing Manufacturer Defendants' wrongdoing in causing it by affirmatively concealing that the observable adverse outcomes of the epidemic were caused by the Marketing Manufacturer Defendants' previous false and misleading marketing and representations, discussed above. In other words, as they no doubt became aware of the overwhelming evidence that their marketing had irresponsibly caused the opioid epidemic, the Marketing Manufacturer Defendants denied the link, both concealing and worsening their wrongful conduct and its adverse effects.

[47] Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

B. Marketing Manufacturer Defendants' Misleading Statements Were Designed for Maximum Effect and Targeted to Specific Audiences

126. Marketing Manufacturer Defendants disseminated these misstatements to doctors through multiple sources, each designed to maximize impact and targeted to a specific receptive audience.

127. Marketing Manufacturer Defendants often delivered their misstatements through KOLs—doctors in the field of pain management who were heavily funded by Marketing Manufacturer Defendants. Marketing Manufacturer Defendants frequently used KOLs to deliver their message because they knew that doctors often place great confidence in seemingly independent peers. By asserting that the KOLs were independent physicians, the Marketing Manufacturer Defendants and KOLs concealed that the KOLs were acting under the practical control of, and/or for the benefit of, the Marketing Manufacturer Defendants and the creation of an increased market for opioids that would yield higher revenue and profits. Drs. Russell Portenoy, Lynn Webster, Perry Fine, and Scott Fishman all served as KOLs.

128. The most prominent KOL was Dr. Russell Portenoy, who held himself out as an unbiased expert on opioids but received substantial funding from Marketing Manufacturer Defendants. Dr. Portenoy gave, in his words, "innumerable" lectures and media appearances promoting opioids.[48] During these appearances, he routinely downplayed the dangers of opioids. In 2010, he said on Good Morning America that "[a]ddiction, when treating pain, is distinctly uncommon" and that "most doctors can feel very assured that that person is not going to become addicted." He also regularly repeated—including in a 1986 paper published in the journal of the

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

American Pain Society, a 1996 paper written on behalf of the American Pain Society and the American Academy of Pain, and numerous lectures—the unsubstantiated claim that the addiction risk posed by opioids was lower than one percent.[49] Dr. Portenoy later conceded that some of his statements were misleading. In December 2012, he was quoted as saying, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[50]

129. Between 2001 and 2010, Purdue's "In the Face of Pain" website similarly presented statements of Dr. Portenoy and other KOLs who were portrayed as independent experts. The website did not disclose that Purdue had paid many of these KOLs for other work, and did not identify Purdue's involvement beyond a small copyright notice at the bottom of the website.[51] These activities were calculated not only to make the messages most effective, but also to conceal that the growing opioid epidemic was the Marketing Manufacturer Defendants' wrongful creation.

130. Marketing Manufacturer Defendants also often disseminated their misstatements through Front Groups that presented themselves as independent patient advocacy organizations, but whose content and funding came largely from Marketing Manufacturer Defendants. These

[49] Russell Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 Pain 171 (May 1986), https://www.ncbi.nlm.nih.gov/pubmed/2873550; Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues*, 11 J. of Pain and Symptom Mgmt. 203 (Apr. 1996), http://dx.doi.org/10.1016/0885-3924(95)00187-5; Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain*, 1 Pain Research and Mgmt. 17 (1996), http://downloads.hindawi.com/journals/prm/1996/409012.pdf.
[50] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[51] Advocacy Voices, In the Face of Pain (archived Nov. 7, 2010), https://web.archive.org/web/20101107090355/http://www.inthefaceofpain.com:80/search.aspx?cat=4#7.

Front Groups included the American Pain Foundation, the American Pain Society, and the American Academy of Pain Medicine. Much like the KOLs, these Front Groups allowed Marketing Manufacturer Defendants to present their misstatements as if they came from unbiased experts. The active concealment of the close relationship between the Marketing Manufacturer Defendants and the Front Groups and KOLs not only made their misleading messages more effective, but also served to conceal the wrongdoing of the Marketing Manufacturer Defendants. The Front Groups, KOLs, and Marketing Manufacturer Defendants all affirmatively and falsely held out the Front Groups and KOLs as independent sources of objective information, concealing their practical control by and/or coordinated action for the benefit of the Marketing Manufacturer Defendants.

131. These Front Groups published many of the misleading "guidelines" described above, based on content and funding provided by Marketing Manufacturer Defendants, including: (1) "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain" (2009);[52] (2) "A Policymaker's Guide to Understanding Pain & Its Management" (2011);[53] and (3) "Treatment Options: A Guide for People Living with Pain" (2006).[54] In 2007, the American Pain Society repeated Marketing Manufacturer Defendants' misstatements that addiction was a "rare problem" for patients using opioids for chronic pain and

[52] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 The J. of Pain 113 (Feb. 2009), http://dx.doi.org/10.1016/j.jpain.2008.10.008.
[53] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.
[54] Am. Pain Found., *Treatment Options: A Guide for People Living with Pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

that there was "no causal effect . . . between the marketing of [a particular opioid] and the abuse and diversion of the drug."[55]

132. Marketing Manufacturer Defendants also conducted conferences, training sessions, and educational programs for doctors, often with all expenses paid at resort destinations. These events were useful to Marketing Manufacturer Defendants because studies show that such events influence the attending practitioners' prescribing habits and views towards a drug.[56]

133. From 1996 to 2001, Purdue conducted over 40 pain management and speaker training sessions at resorts to recruit and train physicians, nurses, and pharmacists as speakers on its behalf.[57] Purdue trained over 5,000 people at these all-expenses-paid events.[58] The DEA has estimated that Purdue funded over 20,000 opioid pain-related programs between 1996 and July 2002 through direct sponsorship or financial grants.[59]

134. Marketing Manufacturer Defendants also used direct salesmen to market opioids. These salesmen often received the majority of their compensation based on individual sales

[55] *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Hearing Before the S. Comm. on Judiciary*, 110th Cong. 1 (2007) (Statement of James Campbell, M.D.).
[56] Ray Moynihan, *Doctors' Education: The Invisible Influence of Drug Company Sponsorship*, 336 The BMJ 416 (Feb. 21, 2008), http://dx.doi.org/10.1136/bmj.39496.430336.DB; A.C. Anand, *Professional Conferences, Unprofessional Conduct*, 67 Medical J. Armed Forces India 2 (Jan. 2011), http://dx.doi.org/10.1016/S0377-1237(11)80002-X; David McFadden et al., *The Devil Is in the Details: The Pharmaceutical Industry's Use of Gifts to Physicians as Marketing Strategy*, 140 J. of Surgical Research 1 (2007), http://dx.doi.org/10.1016/j.jss.2006.10.010.
[57] U.S. Gov't Accountability Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/content-detail.html.
[58] *Id*.
[59] *Id*.

figures, ensuring that they were strongly motivated to present their audiences with misleading information minimizing the risks of opioids.[60]

135. In addition, Marketing Manufacturer Defendants targeted marketing to doctors who would be most receptive to the misstatements.

136. Marketing Manufacturer Defendants specifically targeted their marketing to primary care physicians, who are generally less aware of the medical literature regarding the dangers of treating chronic pain with opioids. One longtime Purdue collaborator speaking to an FDA advisory panel on January 30, 2002 acknowledged that "[g]eneralists are adopting [opioid] therapy without adequate knowledge of pain management principles."[61] Marketing Manufacturer Defendants also targeted susceptible patients like veterans and the elderly.

137. Marketing Manufacturer Defendants developed methods to target doctors who were already prescribing higher-than-average numbers of opioids. Purdue created a database to identify doctors with large numbers of chronic pain patients (which also showed which doctors most frequently prescribed opioids). This database gave Purdue extensive knowledge of where and how its drugs were being used, including in Oklahoma, and has allowed Purdue to target doctors already susceptible to its message.[62]

C. Marketing Manufacturer Defendants Knew or Should Have Known That Their Statements Were Misleading

138. The problems caused by the deceptive, unfair, and false marketing of opioids were specifically known by Marketing Manufacturer Defendants. Marketing Manufacturer

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[60] *Id*.
[61] Food and Drug Admin., Anesthetic and Life Support Drugs Advisory Comm., Tr. of Meeting (Jan. 30, 2002), https://www.fda.gov/ohrms/dockets/ac/02/transcripts/3820t1.pdf.
[62] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. of Public Health 221, 222 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf.

Defendants knew their statements were misleading not only because they knew their statements were contrary to established fact, but also because they were fined and otherwise sanctioned by various government entities for misleading marketing.

139. In 2007, Purdue settled federal allegations that it had introduced misbranded drugs into interstate commerce. Purdue paid over $700 million, and three of its former executive officers pleaded guilty to federal crimes.[63] Purdue acknowledged that "some employees made, or told other employees to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the FDA-approved prescribing information for OxyContin and the express warning it contained about risks associated with the medicine."[64]

140. In August 2015, New York State settled claims against Purdue related to its marketing and sales practices. The settlement required Purdue to ensure that its sales representatives flag doctors and other professionals who were improperly prescribing and/or diverting opioids, stop calling and/or marketing to doctors on the company's "no-call list," and inform healthcare providers about FDA-approved training programs regarding the appropriate prescription of opioids. The agreement also required Purdue to stop representing that its website "www.inthefaceofpain.com" was neutral or unbiased, and to disclose the financial relationship Purdue's purportedly neutral experts have with Purdue.[65]

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[63] Plea Agreement at 4, *United States v. The Purdue Frederick Co.*, No. 1:07-cr-00029-JPJ (W.D. Va. May 10, 2017).

[64] Shannon Henson, *Purdue, Employees to Pay $700M in OxyContin Case*, LAW360, (May 10, 2007, 12:00 AM), https://www.law360.com/illinois/articles/24509/purdue-employees-to-pay-700m-in-oxycontin-case.

[65] Press Release, N.Y. 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.

141. In August 2017, Purdue settled, for over $20 million, claims by numerous Canadian plaintiffs that the company failed to warn about the dangers of OxyContin, including its addictive properties.[66]

142. In 2016, Endo settled claims with New York and agreed to halt misleading advertisements in New York about the safety of opioids. The State had found that opioid use disorders "appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[67] Endo had claimed on its 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 New York found that Endo had no evidence for that statement.[68] Consistent with this finding, Endo agreed not to make statements in New York that opioids "generally are non-addictive" or "that most patients who take opioids do not become addicted."[69]

143. Marketing Manufacturer Defendants have also represented to the public that they are taking steps to curb the opioid epidemic, rather than creating it.

a. As recently as November 2017, Purdue stated on its website that ". . . too often these medications [opioids] are diverted, misused, and abused. Teenagers, in particular, are vulnerable to prescription drug abuse, which has become a national epidemic."[70] In response to the misuse of opioids,

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[66] *See* Will Davidson LLP, *Purdue Pharma Agrees to OxyContin Settlement, but Is it Fair?*, Lexology (Aug. 22, 2017), https://www.lexology.com/library/detail.aspx?g=d53ee1ee-44cb-4ef5-b916-e570a385b568.

[67] Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 7, *In re Endo Health Solutions Inc.*, No. 15-228 (Attorney General of the State of N.Y. 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

[68] *Id.*

[69] *Id.*

[70] Purdue Pharma, *Combating Opioid Abuse*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/combating-opioid-abuse/ (last visited Mar. 26, 2018).

Purdue said that "Corporations have a responsibility to address this issue, and Purdue has dedicated vast resources for helping to prevent drug abuse . . . ."[71]

b. Purdue also stated in November 2017 that it is "committed to being part of the solution to prescription drug abuse" and that it "offers an array of programs focused on education, prevention, and deterrence, and through partnerships with (1) healthcare professionals, (2) families and communities, and (3) law enforcement and government" to combat the "widespread abuse of opioid prescription pain medications [that] can lead to tragic consequences, including addiction, overdose, and death."[72]

c. Also in November 2017, Purdue discussed the opioid epidemic and its response to it, stating that "The nation is experiencing a public health crisis involving licit and illicit opioids. Purdue endorses the following policies that support a comprehensive approach to reducing addiction, abuse, diversion, and overdose related to opioids."[73] Those policies include limiting the duration of one's first opioid prescription; use of prescription drug monitoring programs; requiring demonstrated competence for opioid prescribing; and expanding the use of naloxone, an opioid reversal agent.

144. However, these representations are untrue. For example, despite its public statements of corporate responsibility, and its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement, Purdue has failed to report to authorities illicit or suspicious prescribing of its opioids."[74] This concealment while making representations to the contrary (and also under a duty to disclose), not only served as a cause of

[71] *Id*.
[72] Purdue Pharma, *Responsible Use of Opioids*, http://www.purduepharma.com/patients-caregivers/responsible-use-of-opioids/ (last visited Mar. 26, 2018).
[73] Purdue Pharma, *Public Policies to Address the Opioid Crisis*, http://www.purduepharma.com/about/purdue-pharma-public-policy/ (last visited Mar. 26, 2018).
[74] *See* Press Release, Purdue Pharma L.P., Setting the Record Straight on OxyContin's FDA-Approved Label (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Press Release, Purdue Pharma L.P., Setting the Record Straight on Our Anti-Diversion Programs (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

the continuation of the opioid epidemic, but also to affirmatively conceal the Marketing Manufacturer Defendants' wrongdoing in causing the epidemic in the first place.

145. In 2012, Endo took the remarkable step of asserting that the FDA should block generic versions of Endo's Opana ER because the drug was dangerously susceptible to abuse and misuse.[75] Endo made no such assertions before it faced financial competition regarding the drug.

146. Additionally, since at least 2002, Purdue has maintained a database of healthcare providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, physicians could be added to this database based on observed indicators of illicit prescribing, such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation."[76]

147. Yet, according to a 2016 investigation by the Los Angeles Times, Purdue failed to cut off these providers' opioid supply at the pharmacy level and failed to report these providers to state medical boards or law enforcement—meaning Purdue continued to generate sales revenue from their prescriptions.[77]

148. This investigation also found that for over a decade, Purdue "collected extensive evidence suggesting illegal trafficking of OxyContin" but consistently failed to report suspicious

[75] *See* David Heath, *Drugmaker Set to Profit from an Opioid it Said Was Unsafe*, CNN, Oct. 30, 2017, http://www.cnn.com/2017/10/30/health/opana-endo-opioid-profit/index.html.
[76] *Id*.
[77] *See* Harriet Ryan et al., *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

dispensing or stop supplies to pharmacies.[78] Despite knowing of illicit prescribing, Purdue did not report its suspicions until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed over 1.1 million OxyContin tablets.[79] Again, this concealment of the truth, while making representations to the contrary (and also under a duty to disclose), not only served as a cause of the continuation of the opioid epidemic, but also to affirmatively conceal the Marketing Manufacturer Defendants' wrongdoing in causing the epidemic in the first place.

D. Marketing Manufacturer Defendants' Conduct Violated Their Duties

149. Marketing Manufacturer Defendants have continued to promote, directly and indirectly, deceptive marketing messages that misrepresent, and fail to include material facts about, the dangers of opioid usage, despite actual or constructive knowledge that the opioids were ultimately being consumed for unsafe and non-medical purposes.

150. Marketing Manufacturer Defendants have negligently or recklessly failed to control adequately the content and distribution of marketing materials and sales efforts regarding opioids. A reasonably prudent manufacturer of opioids would have anticipated the dangers of widely advertising and distributing dangerous opioid products and protected against it. A reasonably prudent manufacturer could have: (a) ensured physicians were judicious in considering when to prescribe opioids; (b) used due care in wording its marketing materials to ensure the risks of opioids were clearly communicated; (c) conducted and publicized scientific studies testing the risks of opioid products; (d) taken greater care in hiring, training, and supervising employees responsible for marketing and selling opioid products; (e) investigated

[78] *Id.*
[79] *Id.*

demographic or epidemiological data concerning the increasing demand for narcotic painkillers and the linkage of that demand with Marketing Manufacturer Defendants' marketing efforts; and (f) followed applicable statutes, regulations, professional standards, and guidance, as Marketing Manufacturer Defendants agreed to do when settling prior actions against them.

151. Marketing Manufacturer Defendants failed to take any of these steps to prevent their misrepresentations and omissions from contributing to the opioid epidemic.

E. The Nation Was Harmed by Marketing Manufacturer Defendants' Name-Brand Prescription Opioids and Their Generic Equivalents as a Result of Defendants' Wrongful Marketing Conduct

152. The Marketing Manufacturer Defendants' wrongful marketing efforts and techniques regarding branded and non-branded prescription opioids alleged herein increased the sale of prescription opioids by convincing doctors that prescription opioids could safely be used outside their indicated use and that the risk of addiction from prolonged use was rare and easily reversible.

153. When doctors were convinced through Marketing Manufacturer Defendants' wrongful marketing efforts and techniques regarding branded and non-branded prescription opioids alleged herein to prescribe such Marketing Manufacturer Defendant's name-brand prescription opioid, a pharmacist may, with the doctor's or patient's consent, substitute a generic equivalent of the name-brand opioid in full accord with Oklahoma state law. O.A.C. 535:10-3-1.1(2). Many insurance companies will only pay for the generic equivalent,[80] and so a patient often consents to the substitution of a generic equivalent for the name-brand drug.

[80] *Consumer FAQ*, Oklahoma State Board of Pharmacy, https://www.ok.gov/pharmacy/Resources/FAQ/Consumers/index.html (last updated Dec. 11, 2017).

Consequently, even though the doctor may have prescribed a name-brand opioid, the prescription for that product often is filled with a generic equivalent by the pharmacist.

154. The Marketing Manufacturer Defendants knew, or it was reasonably foreseeable, that their wrongful marketing efforts and techniques regarding branded and non-branded prescription opioids alleged herein would lead in many instances to the substitution and sale of a generic equivalent for a name-brand prescription opioid by the pharmacist.

155. Those Marketing Manufacturer Defendants that manufactured and sold generic prescription opioids in addition to name-brand prescription opioids knew and intended their wrongful marketing conduct alleged herein would increase the sales and profits of both their name-brand and generic prescription opioids.

156. As a result of Marketing Manufacturer Defendants' wrongful conduct in marketing prescription opioids as alleged herein, including the sale of both name-brand prescription opioids and, where applicable, their generic equivalents, the Nation suffered great harm and injury and continues to suffer great harm and injury.

F. Generic Marketing Manufacturer Defendants Failed to Effectively Communicate with Physicians and Patients about Their Products

157. Certain of the Marketing Manufacturer Defendants—Actavis, Allergen, Teva, Amneal, and KVK (collectively, "Generic Marketing Manufacturer Defendants")—are makers of generic prescription opioid products. Generic Marketing Manufacturer Defendants failed to effectively and adequately communicate the warnings in the labels of their products to physicians and patients. To ensure that both were aware of the risks and appropriate uses of prescription opioid narcotics, they owed a duty to effectively communicate clinically relevant information and warnings regarding these adverse health risks, but they breached their duty.

158. Generic Marketing Manufacturer Defendants also failed to timely and effectively correct misstatements and misrepresentations made by name-brand opioid manufacturers such as Purdue, Endo, and others. Their failure to do so constituted a breach of duty to purchasers and consumers of their products. Specifically, they failed to ensure that the warning language and other information was effectively communicated to physicians and patients—including by means of communication that did not require language different from the approved FDA label, and did not require permission or assistance from the FDA, such as sending doctors and healthcare providers letters that did not contain additional or substantial new warning information, but which highlighted and explained the products' warnings, labeling, and other information. Such letters can be appropriate to convey "important safety concern[s]," such as "clinically important new information about a known adverse reaction."[81]

159. Generic Marketing Manufacturer Defendants could have complied with both their Oklahoma tort law duty to prevent foreseeable harms and their requirements under federal law, but failed to do so. These tort claims rest on traditional state law principles that parallel federal safety requirements but do not exist solely by virtue of the FDA laws and regulations. Generic Marketing Manufacturer Defendants could have satisfied their state law duty by taking actions that comport with federal law, but they failed to do so.

160. Generic Marketing Manufacturer Defendants had financial incentives to neither communicate or amplify a message about the dangers of prescription opioids, nor highlight clinically relevant data or information about their adverse health effects, because Generic Marketing Manufacturer Defendants profited greatly from the sale of these products. Thus,

[81] FDA, *Guidance for Industry: Dear Health Care Provider Letters* 3–4 (Jan. 2014),http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm233769.pdf (non-binding guidance).

rather than act in accordance with their duties, Generic Marketing Manufacturer Defendants aggressively marketed their generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase their own market share among generics.

161. Generic Marketing Manufacturer Defendants knew or should have known that their failure to adequately communicate, highlight, and explain the warnings, labeling, and other information concerning prescription opioids, such as safety concerns and new information about adverse health consequences, would harm the Nation and its citizens.

IV. DIVERSION DEFENDANTS HAVE LEGAL DUTIES TO PREVENT OPIOID DIVERSION

162. Each of the Diversion Defendants has a common law duty to exercise reasonable care under the circumstances. In addition, each of the Diversion Defendants assumes a duty, when it speaks publicly about opioids, to speak accurately.

163. Moreover, applicable Federal and state laws and regulations impose duties on Diversion Defendants, and create a standard of conduct to which they must adhere.

164. These statutes and regulations were designed to prevent drug diversion (which, as discussed above, occurs whenever the supply chain of prescription opioids is broken and the drugs are transferred from a legitimate channel to an illegitimate one) by creating a legal framework for distributing and dispensing controlled substances and monitoring and controlling them from manufacture through delivery to the patient. These statutes and regulations include the FCSA, 21 U.S.C. §§ 801 *et seq.*, state controlled substances acts, laws regarding branding of drugs, and regulations related to persons who handle, prescribe, and dispense controlled substances. These statutes and regulations impose strict controls throughout the prescription opioid distribution chain.

165. The Nation is not asserting a cause of action under these laws. But just as a driver's violation of a speed limit can demonstrate that he acted negligently, so, too, Diversion Defendants' violations of applicable Federal and state laws and regulations show that they failed to meet the relevant standard of care.

A. Federal Law Sets a Standard of Care That Diversion Defendants Must Follow

1. Diversion Manufacturer Defendants' and Distributor Defendants' Standard of Care Under Federal Law

166. The FCSA sets the standard of conduct to which Diversion Manufacturer Defendants and Distributor Defendants must adhere. The FCSA requires all opioid manufacturers and distributors to maintain effective controls against prescription opioid diversion, whether name-brand or their generic equivalents, and to employ a system to identify and report to law enforcement suspicious orders of controlled substances.

167. Diversion Manufacturer Defendants and Distributor Defendants must (a) send transaction data to the DEA on each acquisition or reduction of inventory, as well as any lost or stolen inventory, and (b) maintain a complete and accurate record of each substance manufactured, sold, delivered, or otherwise disposed of. 21 U.S.C. § 827.

168. Diversion Manufacturer Defendants and Distributor Defendants must employ a system to inform the DEA of suspicious orders. 21 C.F.R. § 1301.74(b).

169. The DEA's Automation of Reports and Consolidated Orders System ("ARCOS") accumulates data on manufacturers' and distributors' controlled substances transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. 21 C.F.R. § 1304.33. This includes Diversion Manufacturer Defendants' and Distributor Defendants' transactions.

2. Pharmacy Defendants' Standard of Care Under Federal Law

170. The FCSA requires pharmacists to review each controlled substance prescription and, prior to dispensing medication, make a professional determination that the prescription is effective and valid.

171. Under the FCSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a *corresponding responsibility* rests with the pharmacist who fills the prescription." (Emphasis added.)

172. Therefore, pharmacists must ensure that prescriptions for controlled substances are valid, and that they are issued for a legitimate medical purpose by an individual practitioner who is approved and registered with the DEA to write prescriptions for opioids acting in the usual course of his professional practice.

173. The DEA has informed pharmacists that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription."[82] Filling such a prescription is illegal. As the DEA states, "The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a

[82] Michele Leonhart et al., *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*, Drug Enf't Admin., Diversion Control Div. (Revised 2010), https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/.

questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be [criminally] prosecuted."[83]

174. Questionable or suspicious prescriptions include: (a) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities) for controlled substances than other practitioners in the area; (b) prescriptions which should last for a month in legitimate use, but are refilled more frequently; (c) simultaneous prescriptions for antagonistic drugs, such as depressants and stimulants; (d) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (e) prescriptions with atypical quantities or dosages; (f) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (g) photocopied prescriptions; or (h) prescriptions containing different handwritings. Most of the time, these questionable or suspicious attributes are not difficult to detect or recognize; they should be apparent to an adequately trained pharmacist.

175. Pharmacists are also instructed to be suspicious of signs that a customer is seeking to divert opioids, including customers who: (a) appear to be returning too frequently; (b) are seeking to fill a prescription written for a different person; (c) appear at the pharmacy counter simultaneously, or within a short time, all bearing similar prescriptions from the same physician; (d) are not regular patrons or residents of the community, and present prescriptions from the same physician; (e) drive long distances to have prescriptions filled; (f) seek large volumes of controlled substances in the highest strength in each prescription; (g) seek a combination of other drugs with opioids such as tranquilizers and muscle relaxers that can be used to create an "opioid cocktail"; and (h) pay large amounts of cash for their prescriptions rather than using insurance.

[83] *Id*.

Ignoring these suspicious signs violates industry standards and DEA guidelines and is illegal under multiple laws.

176. Other "red flags" that should alert a pharmacist to potential diversion include: (a) prescriptions that lack the technical requirements of a valid prescription, such as a verifiable DEA number and signature; (b) prescriptions written in excess of the amount needed for proper therapeutic purposes; (c) prescriptions obtained through disreputable or illegal web-based pharmacies; and (d) patients receiving multiple types of narcotic painkillers on the same day.

177. Each prescriber of controlled substances is issued a number identification by the DEA and must sign each prescription. Industry standards require pharmacists to contact the prescriber for verification or clarification whenever there is a question about any aspect of a prescription. If a pharmacist believes the prescription is forged or altered, he or she should not fill it, but instead should call the local police. If a pharmacist believes there is a pattern of prescription abuse, the local Board of Pharmacy and the DEA must be contacted.

B. Oklahoma Law Sets a Standard of Care That Diversion Defendants Must Follow

1. Diversion Manufacturer Defendants' and Distributor Defendants' Standard of Care Under Oklahoma Law

178. In addition to having common law duties and duties under Federal law, the Diversion Manufacturer Defendants and Distributor Defendants are governed by the Oklahoma Uniform Controlled Dangerous Substances Act ("Oklahoma CSA"), 63 Okl. Stat. Chapter 2, and the duties imposed in the statute and its implementing regulations. The Diversion Manufacturer Defendants' and Distributor Defendants' violation of these requirements shows that they failed to meet the relevant standard of conduct society expects from them.

179. The Oklahoma CSA creates a legal framework for the distribution and dispensing of opioids in Oklahoma, including by manufacturers and distributors. Diversion Manufacturer Defendants' and Distributor Defendants' violation of these laws constitutes negligence and negligence per se.

180. The Oklahoma CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the ultimate user. Every person or entity who manufactures, distributes, or dispenses opioids must obtain a "registration" from the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. Registrants at every level of the prescription opioid supply chain must fulfill their obligations under the Oklahoma CSA, otherwise there is great potential for harm to the Nation.

181. Under the Oklahoma CSA and the Oklahoma administrative code, manufacturers and distributors must maintain effective controls against prescription opioid diversion. They must also create and use a system to identify and report suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, manufacturers and distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders that suggest diversion.

182. To prevent unauthorized users from obtaining opioids, Oklahoma law creates a distribution monitoring system for controlled substances. The Oklahoma CSA requires distributors and dispensers of controlled dangerous substances, including manufacturers and distributors, to keep records and maintain inventories in conformance with applicable laws and regulations.

183. The Oklahoma administrative code requires anyone who distributes or dispenses a prescription opioid, including manufacturers and distributors, to inform the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of suspicious orders. Such orders include those of unusual size or frequency and those deviating substantially from a normal pattern.

184. Likewise, the Oklahoma administrative code requires that distributors and dispensers, including manufacturers and distributors, notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of any theft or significant loss of any controlled dangerous substances. Thefts must be reported whether or not the controlled dangerous substances are subsequently recovered and/or the responsible parties are identified and action is taken against them.

185. Distributors and dispensers, including manufacturers and distributors, are also required to maintain records, reports, and inventory in accordance with Oklahoma law, including by complying with their registration and opioid tracking requirements. Manufacturers and distributors also have a duty to maintain effective controls against diversion of controlled substances.

2. Pharmacy Defendants' Standard of Care Under Oklahoma Law

186. Like manufacturers and distributors, pharmacies must exercise reasonable care under the circumstances. This involves 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.

187. Pharmacists are the "last line of defense" in keeping drugs from entering the illicit market. They are meant to be the drug experts in the healthcare delivery system, and as such

have considerable duties and responsibility in the oversight of patient care. They cannot blindly fill prescriptions written by a doctor—even a doctor registered under the Oklahoma CSA to dispense opioids—if the prescription is not for a legitimate medical purpose.

188. The Oklahoma CSA imposes duties and requirements on the conduct of the Pharmacy Defendants. These requirements, along with their related regulations and agency interpretations, set a standard of care for pharmacy conduct.

189. The Oklahoma CSA requires pharmacists to review each opioid prescription and, prior to dispensing medication, determine that the prescription is effective and valid.

190. Under the Oklahoma Administrative Code, pharmacy registrants are required to provide effective controls and procedures to guard against theft and diversion of controlled substances. In addition, the Oklahoma administrative code states: "A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by a registered or otherwise authorized individual practitioner acting in the usual course of his/her professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription, as the filling of a prescription is not incumbent on the pharmacy." Okl. Adm. Code T. 475 Section 30-1-3

191. Therefore, pharmacists are required to ensure that prescriptions for controlled substances are valid, and that they are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. Additionally, the Pharmacy Defendants must "address the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that the patient may be dependent or addicted," a duty they did not adequately or uniformly perform. Okla. Admin. Code 535:10-3.1.2(12).

192. State pharmacy boards and national industry associations have provided extensive guidance to pharmacists concerning their duties to the public and the standard of care they are expected to meet. The guidance teaches pharmacists how to identify red flags, which indicate potential problems with a prescription. The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

193. The industry guidance tells pharmacists how to recognize stolen prescription pads; prescription pads printed using a legitimate doctor's name, but with a different call-back number that is answered by an accomplice of the drug-seeker; prescriptions written using fictitious patient names and addresses, and so on.

194. Questionable or suspicious prescriptions include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities) for controlled substances than other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or dosages that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwritings. Most of the time, these attributes are not difficult to detect or recognize; they should be apparent to an adequately trained pharmacist.

195. Signs that a customer is seeking opioids for the purpose of diversion include customers who: (1) appear to be returning too frequently; (2) are seeking to fill a prescription written for a different person; (3) appear at the pharmacy counter simultaneously, or within a short time, all bearing similar prescriptions from the same physician; (4) are not regular patrons

or residents of the community, and show up with prescriptions from the same physician; (5) drive long distances to have prescriptions filled; (6) seek large volumes of controlled substances in the highest strength in each prescription; (7) seek a combination of other drugs with opioids such as tranquilizers, benzodiazepines, and/or muscle relaxers that can be used to create an "opioid cocktail"; and (8) pay large amounts of cash for their prescriptions rather than using insurance. Other "red flags" include prescriptions that lack the technical requirements of a valid prescription; prescriptions written in excess of the amount needed for proper therapeutic purposes; prescriptions obtained through disreputable or illegal web-based pharmacies; and patients receiving multiple types of narcotic painkillers on the same day.

196. Ignoring these signs violates industry standards and standards required by the "reasonable person" standard under basic principles of Oklahoma tort law.

197. All of these issues have been presented extensively in pharmacist training programs nationwide and have been used as examples by individual state boards of pharmacy and the National Association of Boards of Pharmacy.

198. Industry standards require pharmacists to contact the prescriber for verification or clarification whenever there is a question about any aspect of a prescription order. If a pharmacist is ever in doubt, he or she must ask for proper identification. If a pharmacist believes the prescription is forged or altered, he or she should not dispense it and should call the local police. If a pharmacist believes he or she has discovered a pattern of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

199. A standard of care for the Pharmacy Defendants is also set by Oklahoma statutes and regulations. For example, under Title 59, Section 353.24 of the Oklahoma Statutes, as well as Oklahoma Administrative Code Sections 535:15-3-2, 535:25-9-8, 535:10-3-1.2, pharmacies

must "establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels," and it is a violation of professional standards not to attempt to address the suspected addiction of a patient to a drug dispensed by the pharmacist, if there is reason to believe the patient may be addicted. The Pharmacy Defendants breached their duties.

V. DIVERSION DEFENDANTS HAVE FAILED TO FULFILL THEIR DUTIES

A. Diversion Manufacturer Defendants and Distributor Defendants Understood Their Duties and Violated Them Anyway

1. Diversion Manufacturer Defendants and Distributor Defendants Understood and Acknowledged Their Duties

200. In addition to Federal and state laws and regulations regarding controlled substances, Diversion Manufacturer Defendants and Distributor Defendants received detailed, specific instructions for identifying and minimizing the risk of prescription opioid diversion.

201. To combat prescription opioid diversion, the DEA has provided readily-available guidance to manufacturers and distributors on the requirements of suspicious order reporting, including Diversion Manufacturer Defendants and Distributor Defendants.

202. Since 2006, the DEA has briefed manufacturers and distributors regarding legal, regulatory, and due diligence responsibilities. During these briefings, the DEA pointed out the red flags manufacturers and distributors should look for to identify potential diversion.

203. Since 2007, the DEA has hosted at least five conferences to provide registrants (including manufacturers and distributors) with updated information about diversion trends and regulatory changes that affect the drug supply chain and suspicious order reporting.[84] The

[84] Drug Enf't Admin., *Distributor Conferences*, https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin.,

majority of the major manufacturers and distributors, including many, if not all, of the Diversion Manufacturer Defendants and Distributor Defendants, attended at least one of these conferences.

204. These conferences discussed, among other things, guidance on suspicious order monitoring and the manufacturers' and distributors' obligations to conduct due diligence on controlled substance customers to help prevent diversion. For example, the conferences explained that each manufacturer and distributor must exercise due care in confirming the legitimacy of all orders. They also described circumstances that could indicate diversion, including ordering (a) excessive quantities of a limited variety of controlled substances while ordering few if any other drugs, or (b) the same controlled substance from multiple sources. They also covered manufacturers' and distributors' obligations to report suspicious orders when discovered and specified that monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The conferences also advised manufacturers and distributors that they must independently analyze a suspicious order before sale to determine if the controlled substances would likely be diverted and that filling a suspicious order and then completing the sale does not absolve a manufacturer or distributor from legal responsibility.

205. On September 27, 2006, and December 27, 2007, the DEA's Office of Diversion Control sent letters to all registered distributors providing guidance similar to that provided at the conferences.[85]

Manufacturer Conferences, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

[85] Masters Pharmaceuticals, Inc.; Decision and Order, 80 Fed. Reg. 55,418, 55,421 (Drug Enf't Admin. Sept. 15, 2015) (No. 13–39), 2015 WL 5320504.

206. Distributor Defendants also were on notice that their own industry group, the Healthcare Distribution Management Association, now known as Healthcare Distribution Alliance ("HDA"), published Industry Compliance Guidelines for reporting suspicious orders and preventing diversion.[86]

207. These industry guidelines further explained that, by being "[a]t 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."[87]

208. Finally, the Distributor Defendants have themselves recognized the magnitude of the problem and have made statements assuring the public they recognize their duty to curb the opioid epidemic.

209. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[88]

210. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and is "deeply passionate about curbing the opioid epidemic in our country."[89]

211. At the very least, these assurances created a duty for Cardinal and Amerisource, and any other of the Diversion Manufacturer Defendants and Distributor Defendants who made

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[86] Healthcare Distrib. Mgmt. Ass'n (HDA), *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App. B at 1).

[87] *Id*.

[88] 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, http://wapo.st/2vCRGLt.

[89] 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, http://wapo.st/2uR2FDy.

similar statements, to act reasonably by following through on them. Further, these false representations concealed from the public and the Nation the Diversion Manufacturer Defendants' and Distributor Defendants' wrongdoing that caused the opioid epidemic.

2. Prior Regulatory Actions Against Distributor Defendants for Failing to Prevent Diversion

212. Despite knowing the risks of diversion and their broad assurances to regulators, states, and the public, Distributor Defendants have recklessly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties.

a. Cardinal

213. Cardinal has paid millions of dollars in multiple DEA and state actions relating to its improper management and distribution of opioids.

214. In 2008, Cardinal paid a $34 million penalty to settle allegations about prescription opioid diversion taking place at seven warehouses around the United States.[90] These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.

215. In 2012, Cardinal reached another settlement with the DEA relating to systemic prescription opioid diversion in its Florida distribution center.[91] Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only

[90] Press Release, U.S. Attorney's Office Dist. of Colo., Cardinal Health, Inc. Agrees to Pay $34 Million to Settle Claims That it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

[91] Press Release, Drug Enf't Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), https://www.dea.gov/pubs/pressrel/pr051512.html.

four area pharmacies, nearly 50 times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years. The DEA found that Cardinal's own investigator warned Cardinal against selling opioids to these pharmacies but that Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacies. Instead, Cardinal's opioid shipments to the pharmacies increased.

216. In December 2016, Cardinal paid $44 million to settle charges that it had violated the law by failing to report suspicious orders in four states.[92] The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case. The settlement also covered a Cardinal subsidiary, Kinray, LLC, which did not report a single suspicious order regarding its shipments of oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate. Cardinal Health d/b/a Kinray is a licensed wholesale drug distributor in Oklahoma and, on information and belief, distributes opioids in the State.

217. In January 2017, Cardinal paid $20 million to settle allegations by West Virginia that Cardinal had shipped increasing amounts of opioids to numerous counties without utilizing proper controls, in essence benefitting from West Virginia's problem with opioid abuse.[93]

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[92] Press Release, U.S. Attorney's Office Dist. of Md., Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

[93] Eric Eyre, *2 Drug Distributors to Pay $36M to Settle WV Painkiller Lawsuits*, Charleston Gazette-Mail, Jan. 9, 2017, http://www.wvgazettemail.com/news-cops-and-courts/20170109/2-drug-distributors-to-pay-36m-to-settle-wv-painkiller-lawsuits.

b. McKesson

218. McKesson has agreed to pay over $163 million to resolve government charges regarding diversion.

219. In May 2008, McKesson paid $13.25 million to settle claims by the DEA that it had failed to maintain effective controls against diversion.[94] McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies, resulting in millions of doses of controlled substances being diverted.

220. Following the 2008 settlement, McKesson was supposed to change its ways and fix its flawed processes to prevent prescription opioid diversion. But it did not do so. It was later revealed that McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that, in a five-year period, it filled more than 1.6 million orders but reported just 16 orders as suspicious (all from a single consumer). In fact, in 2013, inspections of some of McKesson's distribution facilities found that the company did not even fully "implement or adhere to its own" compliance program.[95] In early 2017, it was reported that McKesson had agreed to pay $150 million to the federal government to settle certain prescription opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.[96]

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[94] Press Release, U.S. Attorney's Office Dist. of Colo., McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims That it Failed to Report Suspicious Sales of Prescription Medications (May 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/May08/5_2b_08.html.

[95] Anders Melin and Jef Feeley, *McKesson Records Show Failed Opioid Oversight, Lawsuit Says*, Bloomberg, Dec. 8, 2017, https://www.bloomberg.com/news/articles/2017-12-08/mckesson-investor-claims-board-failed-oversight-duty-on-opioids.

[96] Press Release, U.S. Dep't of Justice, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

c. AmerisourceBergen

221. AmerisourceBergen has paid $16 million in settlements and had certain licenses revoked as a result of allegations related to prescription opioid diversion.

222. 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.[97] Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.[98]

223. In January 2017, AmerisourceBergen paid the State of West Virginia $16 million to settle allegations that it knowingly shipped increasing amounts of opioids without sufficient monitoring or control, facilitating six-fold increases in opioid consumption in some counties.[99] AmerisourceBergen was part of a drug supply chain that included doctors who wrote prescriptions for non-medical purposes and "pill mill" pharmacies that dispensed excessive numbers of painkillers. In addition to the monetary settlement, AmerisourceBergen agreed to adhere to stricter reporting guidelines within West Virginia.

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[97] Press Release, AmerisourceBergen, AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of Its Orlando Distribution Center's Suspended License to Distribute Controlled Substances (June 22, 2007), http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-signs-agreement-dea-leading-reinstatement-its.

[98] Jeff Overley, *AmerisourceBergen Subpoenaed by DEA over Drug Diversion*, LAW360 (Aug. 9, 2012, 4:28 PM), https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion.

[99] Eric Eyre, *2 Drug Distributors to Pay $36M to Settle WV Painkiller Lawsuits*, Charleston Gazette-Mail, Jan. 9, 2017, http://www.wvgazettemail.com/news-cops-and-courts/20170109/2-drug-distributors-to-pay-36m-to-settle-wv-painkiller-lawsuits.

3. Diversion Manufacturer Defendants Violated Their Duties in Oklahoma

224. All of the Diversion Manufacturer Defendants have engaged in a consistent pattern and practice of illegally distributing opioids. That pattern and practice has also affected the Nation and its citizens.

225. In fact, Diversion Manufacturer Defendants have supplied and continue to supply prescription opioids to distributors that supply prescription opioids on and around the Nation with actual or constructive knowledge that they were ultimately being consumed by Nation citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but Diversion Manufacturer Defendants negligently or recklessly failed to do so.

226. Each of the Diversion Manufacturer Defendants knew or should have known that the amount of opioids that it supplied to distributors, which in turn distributed them on and around the Nation, far exceeded what could be consumed for medically necessary purposes.

227. Each of the Diversion Manufacturer Defendants negligently or recklessly failed to control their supply lines to prevent diversion. A reasonably prudent manufacturer distributing controlled substances would have anticipated the danger of prescription opioid diversion and protected against it by, for example: (a) taking greater care in hiring, training, and supervising employees; (b) providing greater oversight, security, and control of supply channels; (c) investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers on and around the Nation; (d) informing distributors about prescription opioid diversion; and (e) following statutes, regulations, professional standards, and guidance from government agencies. Diversion Manufacturer Defendants were under a duty to speak with

respect to their fulfilling of suspicious orders, and yet concealed their wrongdoing from the DEA, the public, and the Nation.

228. Each of the Diversion Manufacturer Defendants made little to no effort to follow up with distributors servicing the Nation to perform inspections to ensure that the controlled substances Diversion Manufacturer Defendants had furnished, including prescription opioids, were not being diverted to illegal uses.

229. The compensation Diversion Manufacturer Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to distributors and other facilities servicing the Nation, thus improperly creating incentives that exacerbated prescription opioid diversion and the resulting epidemic of opioid abuse.

4. Despite Prior Regulatory Actions, Distributor Defendants Violated Their Duties in Oklahoma

230. Despite being penalized by law enforcement authorities, Distributor Defendants have not changed their conduct. Rather, they have treated fines as a cost of doing business in an industry that generates billions of dollars in revenue.

231. All of the Distributor Defendants have engaged in a consistent, nationwide pattern and practice of illegally distributing opioids. That pattern and practice has also affected the Nation and its citizens.

232. In fact, Distributor Defendants have supplied and continue to supply prescription opioids on and around the Nation with actual or constructive knowledge that they were ultimately being consumed by Nation citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but Distributor Defendants negligently or recklessly failed to do so.

233. Each Distributor Defendant knew or should have known that the amount of opioids that it allowed to flow into the Nation far exceeded what could be consumed for medically necessary purposes.

234. Distributor Defendants negligently or recklessly failed to control their supply lines to prevent diversion. A reasonably prudent distributor of controlled substances would have anticipated the danger of prescription opioid diversion and protected against it by, for example: (a) taking greater care in hiring, training, and supervising employees; (b) providing greater oversight, security, and control of supply channels; (c) looking more closely at pharmacists and doctors who were purchasing large quantities of commonly abused opioids in amounts much greater than appropriate given the size of the local populations; (d) investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers on and around the Nation; (e) informing pharmacies and retailers about prescription opioid diversion; and (f) following statutes, regulations, professional standards, and guidance from government agencies. Distributor Defendants were under a duty to speak with respect to their fulfilling of suspicious orders, and yet concealed their wrongdoing from the DEA, the public, and the Nation.

235. Each of the Distributor Defendants made little to no effort to visit pharmacies servicing the Nation to perform inspections to ensure that the controlled substances Distributor Defendants had furnished, including prescription opioids, were not being diverted to illegal uses.

236. The compensation 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 Nation, thus improperly creating incentives that exacerbated prescription opioid diversion and the resulting epidemic of opioid abuse.

B. Pharmacy Defendants Understood Their Duties and Violated Them Anyway

1. Pharmacy Defendants Understood and Acknowledged Their Duties

237. Pharmacy Defendants similarly knew of the risks and harms of filling prescriptions for non-medical purposes, including widespread opioid abuse.

238. The DEA has provided extensive guidance to pharmacists concerning their duties to the public.[100] So have state pharmacy boards[101] and national industry associations.[102] The guidance teaches pharmacists how to identify red flags, which indicate that there may be a problem with the legitimacy of a prescription presented by a patient.[103] The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

239. For instance, the industry guidance tells pharmacists how to recognize: (a) stolen prescription pads; (b) prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice of the drug-seeker; (c) prescriptions written using fictitious patient names and addresses; and (d) other red flags.[104]

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[100] Michele Leonhart et al., *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*, Drug Enf't Admin., Diversion Control Div. (Revised 2010), https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/.

[101] Tex. State Bd. of Pharmacy, *Abuse & Misuse of Prescription Drugs* (last visited Mar. 26, 2018), https://www.pharmacy.texas.gov/SB144.asp; Fla. Bd. of Pharmacy, *DEA Guidelines to Prescription Fraud* (June 12, 2013), http://floridaspharmacy.gov/latest-news/dea-guidelines-to-prescription-fraud/; Va. Bd. of Pharmacy, *Prescription Drug Abuse: Red Flags for Pharmacists and Pharmacy Technicians* (Aug. 6, 2014), https://youtu.be/j5CkhirlZk8.

[102] Philip Brummond et al., *American Society of Health-Systems Pharmacists Guidelines on Preventing Diversion of Controlled Substances*, 74 Am. J. of Health-Sys. Pharmacy e10 (Jan. 2017), http://www.ajhp.org/content/early/2016/12/22/ajhp160919.

[103] Va. Bd. of Pharmacy, *Prescription Drug Abuse: Red Flags for Pharmacists and Pharmacy Technicians* (Aug. 6, 2014), https://youtu.be/j5CkhirlZk8; Philip W. Brummond et al., *American Society of Health-Systems Pharmacists Guidelines on Preventing Diversion of Controlled Substances*, 74 Am. J. of Health-System Pharmacy e10 (Jan. 2017), http://www.ajhp.org/content/early/2016/12/22/ajhp160919.

[104] Fla. Bd. of Pharmacy, *DEA Guidelines to Prescription Fraud* (June 12, 2013), http://floridaspharmacy.gov/latest-news/dea-guidelines-to-prescription-fraud/; Mass. Bd. of

240. Pharmacy Defendants, through their words or actions set forth in news reports and other public documents, have acknowledged these risks and assured the public that issues affecting public health and safety are their highest priority.

241. In 2015, CVS publicly stated that, "the abuse of controlled substance pain medication is a nationwide epidemic that is exacting a devastating toll upon individuals, families and communities. Pharmacists have a legal obligation under Oklahoma and Federal law to determine whether a controlled substance was issued for a legitimate purpose and to decline to fill prescriptions they have reason to believe were issued for a non-legitimate purpose."[105]

242. Similarly, in 2016, Walgreens issued a press release captioned "Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths."[106]

243. In 2017, Walmart acknowledged the need for a "solution to the [opioid] epidemic" and noted the epidemic has "devastated so many families and communities across America."[107]

Registration in Med., Policy 15-05, *Prescribing Practices Policy and Guidelines* (Oct. 8, 2015), http://www.mass.gov/eohhs/docs/borim/policies-guidelines/policy-15-05.pdf.

[105] *Patients Profiled at Pharmacy Counters*, KTNV, Feb. 23, 2015, http://contact1846.rssing.com/chan-30860085/all_p11.html#item217.

[106] Press Release, Walgreens, Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths (Feb. 9, 2016), http://news.walgreens.com/press-releases/general-news/walgreens-leads-fight-against-prescription-drug-abuse-with-new-programs-to-help-curb-misuse-of-medications-and-the-rise-in-overdose-deaths.htm.

[107] Press Release, Walmart, Walmart Supports State of Emergency Declaration on Opioids (Oct. 26, 2017), https://news.walmart.com/2017/10/26/walmart-supports-state-of-emergency-declaration-on-opioids.

244. The Pharmacy Defendants' misrepresentations about their activities constituted concealment of their wrongdoing that caused the opioid epidemic. Their failure to report suspicious orders constituted additional concealment.

2. Prior Regulatory Actions Against Pharmacy Defendants for Failing to Prevent Diversion

245. Despite knowing and even warning of these risks, Pharmacy Defendants recklessly or negligently permitted diversion to occur. In failing to take adequate measures to prevent substantial opioid-related injuries to the Nation, Pharmacy Defendants have breached their duties under the "reasonable care" standard of Oklahoma common law (including violating a voluntarily-undertaken duty to the public which they have assumed by their own words and actions), professional duties under the relevant standards of professional practice, and requirements established by Oklahoma laws and regulations.

246. Pharmacy Defendants were on notice of their ongoing negligence or reckless misconduct towards the Nation in part because of their history of being penalized for violating their duties in other jurisdictions.

a. CVS

247. CVS has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue (a) dispensing opioids in quantities significantly higher than any plausible medical need would require, and (b) violating their recordkeeping and dispensing obligations.

248. As recently as February 2016, CVS paid $8 million to settle allegations by the DEA and the DOJ that its stores and pharmacists had been violating their legal duties and filling

prescriptions with no legitimate medical purpose.[108] CVS has resolved similar allegations by settling with Florida ($22 million),[109] Oklahoma ($11 million),[110] Massachusetts and New Hampshire ($3.5 million),[111] Texas ($1.9 million),[112] and Rhode Island ($450,000).[113]

249. These cases included evidence that CVS filled prescriptions that were clearly forged. For example, in 2016, CVS settled with the United States to resolve allegations stemming from two DEA investigations that revealed that over 50 CVS stores in Massachusetts and New Hampshire had filled patently forged prescriptions for addictive painkillers more than 500 times between 2011 and 2014.[114] The DEA estimated the street value of the diverted drugs to be over $1 million. One forger successfully filled 131 prescriptions for hydrocodone at eight

[108] Press Release, Drug Enf't Admin., DEA Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (Feb. 12, 2016), https://www.dea.gov/divisions/wdo/2016/wdo021216.shtml.
[109] Press Release, U.S. Attorney's Office Middle Dist. of Fla., United States Reaches $22 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution.
[110] Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay $11 Million to Settle Civil Penalty Claims Involving Violations of Controlled Substances Act (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled.
[111] Press Release, U.S. Attorney's Office Dist. of Mass., CVS to Pay $3.5 Million to Resolve Allegations That Pharmacists Filled Fake Prescriptions (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions.
[112] Patrick Danner, *H-E-B, CVS Fined over Prescriptions*, San Antonio Express-News, Sept. 5, 2014, http://www.expressnews.com/business/local/article/H-E-B-CVS-fined-over-prescriptions-5736554.php.
[113] Press Release, U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved with $450,000 Civil Settlement (Aug. 10, 2015), https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement.
[114] Press Release, U.S. Attorney's Office Dist. of Mass., CVS to Pay $3.5 Million to Resolve Allegations That Pharmacists Filled Fake Prescriptions (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions.

CVS stores. One of those stores filled 29 prescriptions for the forger over the course of just six months—an inordinate amount under the circumstances. At a different store, the same individual filled 28 forged prescriptions, even though they were identical in every respect other than the patient name. Additionally, 107 of the forged prescriptions bore the Massachusetts address of a dentist who had closed her Massachusetts practice and moved to Maine—something that should have been easily discovered by CVS pharmacists by checking the DEA website or calling the phone number on the prescriptions.

250. CVS also paid $8 million to settle allegations by the DEA and the DOJ that its stores and pharmacists had been violating their legal duties and filling prescriptions with no legitimate medical purpose.[115] As part of the settlement, CVS acknowledged that from 2008 to 2012, some of its stores in Maryland dispensed controlled substances, including opioids, in a manner that was not fully consistent with its legal obligations, including failing to comply with the responsibility to ensure that these prescriptions were issued for a legitimate medical purpose.

251. CVS also paid $600,000 to settle allegations by the DOJ that on over 6,000 occasions, CVS stores in Connecticut failed to keep appropriate records of prescriptions and purchase invoices.[116]

252. Dating back to 2006, CVS pharmacies in Oklahoma and elsewhere intentionally violated the law by filling prescriptions signed by prescribers with invalid DEA registration

[115] Press Release, U.S. Attorney's Office Dist. of Md., United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawfuldistribution-controlled.

[116] Press Release, U.S. Attorney's Office Dist. of Conn., CVS Pharmacy Pays $600,000 to Settle Controlled Substances Act Allegations (Oct. 20, 2016), https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-act-allegations.

numbers.[117] To fill otherwise illegitimate prescriptions, CVS pharmacists substituted valid DEA registration numbers of non-prescribing practitioners, or substituted false DEA registration numbers in company computer systems, on paper prescriptions, and even in the information that the pharmacy reported to Oklahoma's Prescription Drug Monitoring Program.[118]

b. Walgreens

253. Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the FCSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.[119] As part of the settlement, Walgreens agreed to enhance its training and compliance programs, and to cease compensating its pharmacists based on the volume of prescriptions filled.

254. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than 10 times the average amount.[120] They increased their orders over time, in some cases as much as 600% in the span of just two years, including, for example, supplying a town of 3,000 residents with

[117] Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay $11 Million to Settle Civil Penalty Claims Involving Violations of Controlled Substances Act (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled.
[118] *See* Complaint, *United States v. CVS Pharmacies*, No. 5:11-cv-1124-HE (W.D. Okla. Oct. 5, 2011).
[119] Press Release, U.S. Attorney's Office S. Dist. of Fla., Walgreens Agrees to Pay a Record Settlement of $80 Million for Civil Penalties Under the Controlled Substances Act (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.
[120] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreen Co.* (Drug Enf't Admin. Sept. 13, 2012).

285,800 orders of oxycodone in a one-month period. Yet Walgreens' corporate officers not only turned a blind eye, but also facilitated the opioid boom in Florida by providing Walgreens' pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the law or the health of communities.[121]

255. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000)[122] and Massachusetts ($200,000).[123] The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk. Such patients are supposed to obtain all prescriptions from only one pharmacy, and that pharmacy is required to track the patient's pattern of prescription use. Some of the state's 160 Walgreens accepted cash for controlled substances from patients in MassHealth (the state's combined program for Medicaid and Children's Health Insurance Program), rather than seeking approval from the agency. In some cases, MassHealth had rejected the prescription; other times, MassHealth was never billed. In response, Walgreens

[121] *Id*.
[122] Caleb Stewart, *Kroger, CVS, and Walgreens Settle Lawsuit with West Virginia for $3 Million*, WHSV, Aug. 16, 2016, http://www.whsv.com/content/news/Kroger-CVS-and-Walgreens-settle-lawsuit-with-West-Virginia-for-3-million-390332992.html.
[123] Felice J. Freyer, *Walgreens to Pay $200,000 Settlement for Lapses with Opioids*, The Boston Globe, Jan. 19, 2017, https://www.bostonglobe.com/metro/2017/01/18/walgreens-agrees-better-monitor-opioid-dispensing/q0B3FbMo2k3wPt4hvmTQrM/story.html.

simply agreed to update its policies and procedures and train its staff to ensure that pharmacists properly monitor and do not accept cash payments from patients deemed high-risk.

c. Walmart

256. In 2009, Walmart paid $637,000 to resolve allegations of numerous record keeping violations at its pharmacies in Texas. Those allegations included that Walmart had failed to timely file records indicating loss or theft of drugs to the DEA, in violation of the FCSA.[124]

3. Despite Prior Regulatory Actions, Pharmacy Defendants Continue to Violate Their Duties

257. Despite their extensive and clear understanding of the risks and harms of prescription opioid diversion, Pharmacy Defendants continue to fail to fulfill their obligations to prevent prescription opioid diversion.

258. Pharmacy Defendants have engaged in a consistent, nationwide pattern and practice of illegally distributing opioids that has also affected the Nation and its citizens.

259. Pharmacy Defendants regularly filled prescriptions in circumstances where red flags were present, while failing to uphold their duty to report such suspicious orders (and their wrongful fulfillment of them).

260. Pharmacy Defendants regularly filled opioid prescriptions that would have been questioned by a reasonably prudent pharmacy.

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[124] *See generally* Emma Perez-Trevino, *Wal-Mart Fined for Alleged Recording Keeping Violations*, Brownsville Herald, Jan. 7, 2009, http://www.brownsvilleherald.com/news/local/article_1a19f348-e9ad-534f-a1a1-8423736b0df9.html; *Walmart Fined for Pharmacy Record-Keeping Violations*, Ozarks First, Jan. 7, 2009, http://www.ozarksfirst.com/news/health-and-medical/walmart-fined-for-pharmacy-record-keeping-violations

261. Pharmacy Defendants have not adequately trained or supervised their employees at the point of sale to investigate or report suspicious or invalid prescriptions, or protect against corruption or theft by employees or others.

262. Pharmacy Defendants have utilized monetary compensation programs for certain employees that are based, in part, on the number of prescriptions filled and dispensed. This type of compensation creates economic disincentives within the companies to change their practices to stem diversion. For example, there have been reports of chain store supervisory personnel directing pharmacists to fill prescriptions regardless of the red flags presented.

VI. DEFENDANTS' MISCONDUCT HAS INJURED AND CONTINUES TO INJURE THE NATION AND ITS CITIZENS

263. Defendants had the ability and the duty to prevent misleading marketing and prescription opioid diversion, both of which presented known or foreseeable dangers of serious injury. But they failed to do so, resulting in substantial injury to the Nation and its citizens.

A. Marketing Manufacturer Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

264. Marketing Manufacturer Defendants' marketing campaign has resulted in a significant increase in both name-brand and generic prescription opioid usage: between 1999 and 2016 the number of opioids prescribed nationwide quadrupled.[125] Nationally, the number of

[125] Li Hui Chen et al., *Drug-Poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr. for Health Statistics Data Brief (Sept. 2014), https://www.cdc.gov/nchs/data/databriefs/db166.pdf; Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity and Mortality Weekly Report 1445 (Dec. 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

people who take prescription opioids for non-medical purposes is now greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.[126]

265. Every year, millions of Americans abuse opioid pain relievers, leading to addiction, overdose, and death. Data from the Substance Abuse and Mental Health Services Administration suggest that in 2016, among Americans over the age of twelve, over 1.75 million were are prescription opioid-dependent,[127] and over 11.5 million used prescription opioids for non-medical purposes.[128]

266. Similarly, DEA data shows that in 2016, Oklahoma has seen annual distribution exceeding 660 milligrams per resident,[129] and 5,923 milligrams per opioid user,[130] which is far more than is medically necessary.

267. This growth in non-medical demand, addiction, and diversion has led to serious harm to the Nation and its citizens. The increase in opioid usage has led to levels of addiction that, according to the U.S. Surgeon General, have "devastated" communities across America.[131]

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[126] Substance Abuse and Mental Health Servs. Admin., *Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings*, NSDUH Series H-38A, HHS Publication No. SMA 10-4586 Findings (2010).
[127] Substance Abuse and Mental Health Servs. Admin., *Results from the 2016 National Survey on Drug Use and Health: Detailed Tables*, at Table 5.2A (2017), https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf.
[128] *Id.* at Table 1.54A.
[129] Drug Enf't Admin., ARCOS Report, *Retail Drug Distribution By Zip Code Within State by Grams Weight*, https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2013/2013_rpt1.pdf; https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2014/2014_rpt1.pdf; https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2015/2015_rpt1.pdf; https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/report_yr_2016.pdf.
[130] Wenjun Zhong et al., *Age and Sex Patterns of Drug Prescribing in a Defined American Population*, 7 Mayo Clinic Proceedings 697, 700 (2013).
[131] Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95-CUYC.

Princeton University economist Alan Krueger found that opioids may be responsible for roughly 20% of the national decline in workforce participation by prime-age men and 25% of the drop by women.[132] In 2011, the CDC reported that overdose deaths from prescription opioids had reached "epidemic levels."[133] That year, 16,917 people in the United States died from a prescription opioid-related overdose.[134] Since then, the national death toll has continued to rise. In 2014, 18,893 people died from a prescription opioid-related overdose.[135] In 2015, that number increased again to 22,598.[136] As discussed above, overdose deaths in the United States involving prescription opioids have quadrupled since 1999. CDC data shows that over 123,095 people died from prescription opioid overdoses from 2011–2016.[137]

268. It was reasonably foreseeable to Marketing Manufacturer Defendants that their deceptive and aggressive marketing of opioids on and around the Nation would allow opioids to fall into the hands of addicts and other inappropriate users.

269. It was reasonably foreseeable to Marketing Manufacturer Defendants that their deceptive, unfair, and false marketing campaigns would cause injuries, including abuse, addiction, overdoses, and death. It was also reasonably foreseeable that many of these injuries

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[132] *See* Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Econ. Activity Conference Draft (Aug. 26, 2017).
[133] Press Release, CDC, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.
[134] Li Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr. for Health Statistics Data Brief (Sept. 2014), https://www.cdc.gov/nchs/data/databriefs/db166.pdf.
[135] Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity and Mortality Weekly Report 1445 (Dec. 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.
[136] *Id.*
[137] CDC, Wide-ranging Online Data for Epidemiologic Research (WONDER), http://wonder.cdc.gov.

would be suffered by the Nation and its citizens, and that the costs of these injuries would be shouldered by the Nation.

270. Marketing Manufacturer Defendants knew or should have known that their continuing efforts to employ deceptive, unfair, and false marketing, despite being previously sanctioned by government agencies for such actions, would contribute to the opioid epidemic affecting the Nation.

271. Marketing Manufacturer Defendants knew or should have known that a substantial amount of the opioids dispensed on and around the Nation were being dispensed as a result of their deceptive, unfair, and false marketing. It was foreseeable that the increased number of prescriptions for opioids resulting from Marketing Manufacturer Defendants' deceptive, unfair, and false marketing would cause harm to individual pharmacy customers, third parties, and the Nation.

272. Marketing Manufacturer Defendants made substantial profits over the years based on the deceptive, unfair, and false marketing of opioids on and around the Nation. Their participation and cooperation in a common enterprise has foreseeably caused damages to the Nation and injuries to its citizens. Marketing Manufacturer Defendants knew or should have known that the Nation would be unjustly forced to bear the costs of these injuries and damages.

273. Marketing Manufacturer Defendants' deceptive, unfair, and false marketing of prescription opioids to the Nation showed a reckless disregard for the safety of the Nation and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of the Nation and its citizens.

B. Diversion Manufacturer Defendants' and Distributor Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

274. It was reasonably foreseeable to Diversion Manufacturer Defendants and Distributor Defendants that their violations of their duties under Federal and Oklahoma laws and regulations would allow name-brand and generic prescription opioids to be diverted.

275. It was reasonably foreseeable to Diversion Manufacturer Defendants and Distributor Defendants that their failure to prevent diversion would cause injuries, including addiction, overdoses, and death. It was also reasonably foreseeable that many of these injuries would be suffered by the Nation and its citizens, and that the costs of these injuries would be shouldered by the Nation.

276. Diversion Manufacturer Defendants and Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the Nation's opioid epidemic, and would create access to opioids by unauthorized users, which, in turn, would perpetuate the cycle of addiction, demand, and illegal transactions.

277. Diversion Manufacturer Defendants and Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed on and around the Nation were being dispensed based on invalid or suspicious prescriptions. It was foreseeable that filling suspicious orders for opioids would harm the Nation and its citizens.

278. Diversion Manufacturer Defendants and Distributor Defendants knew of widespread prescription opioid abuse on and around the Nation, but nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in places—and in such quantities, and with such frequency—that they knew or should have known these opioids were not being prescribed and consumed for legitimate medical purposes.

279. The use of opioids by the Nation's citizens who were addicted or who did not have a medically necessary purpose for using opioids could not have occurred without the actions of Diversion Manufacturer Defendants and Distributor Defendants. If Diversion Manufacturer Defendants and Distributor Defendants had guarded against diversion as required by Oklahoma law, the Nation and its citizens would have avoided significant injury.

280. Diversion Manufacturer Defendants and Distributor Defendants profited substantially from the illegal diversion of prescription opioids in the Nation. Diversion Manufacturer Defendants and Distributor Defendants knew or should have known that the Nation would be unjustly forced to bear the costs of these injuries.

281. Diversion Manufacturer Defendants' and Distributor Defendants' distribution of excessive amounts of prescription opioids in the Nation showed a reckless disregard for the safety of the Nation and its citizens. Diversion Manufacturer Defendants' and Distributor Defendants' conduct poses a continuing threat to the health, safety, and welfare of the Nation and its citizens.

282. At all relevant times, Diversion Manufacturer Defendants and Distributor Defendants engaged in these activities, and continue to do so, knowing that the Nation, in its role of providing protection and care for its citizens, would have to provide or pay for additional costs to the healthcare, criminal justice, social services, welfare, and education systems, and would also have to bear the loss of substantial economic productivity and tax revenue.

283. It was reasonably foreseeable to Diversion Manufacturer Defendants and Distributor Defendants that the Nation would be forced to bear substantial expenses as a result of Diversion Manufacturer Defendants' and Distributor Defendants' acts.

284. The conduct of Diversion Manufacturer Defendants and Distributor Defendants, their agents, and their employees was, at the very least, negligent.

C. Pharmacy Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

285. It was reasonably foreseeable to Pharmacy Defendants that filling invalid or suspicious prescriptions for name-brand and generic prescription opioids would cause harm to the Nation and its citizens.

286. It was reasonably foreseeable to Pharmacy Defendants that their failure to prevent diversion would cause injuries, including addiction, overdoses, and death. It was also reasonably foreseeable many of these injuries would be suffered by the Nation and its citizens.

287. Pharmacy Defendants were aware of widespread prescription opioid abuse on and around the Nation, but nevertheless persisted in filling invalid or suspicious prescriptions for opioids and failed to address this misconduct.

288. The use of opioids by the Nation's citizens who were addicted or who did not have a medically necessary purpose could not have occurred without the actions of Pharmacy Defendants. If Pharmacy Defendants had guarded against diversion, the Nation and its citizens would have avoided significant injury.

289. Pharmacy Defendants made substantial profits from the diversion of prescription opioids in the Nation. Their participation and cooperation in a common enterprise has foreseeably caused injuries to the Nation's citizens and damages to the Nation. Pharmacy Defendants knew or should have known that the Nation would be unjustly forced to bear the costs of these injuries.

290. At all relevant times, Pharmacy Defendants have engaged in improper dispensing practices, and continue to do so, despite knowing they could take measures to eliminate them in substantial part.

291. At all relevant times, Pharmacy Defendants engaged in these activities, and continue to do so, knowing that the Nation, in its role of providing protection and care for its citizens, would have to provide or pay for additional costs to the healthcare, justice, social services, welfare, and education systems, and would also have to bear the loss of substantial economic productivity and tax revenue.

292. It was reasonably foreseeable to Pharmacy Defendants that the Nation would be forced to bear substantial expenses as a result of Pharmacy Defendants' acts.

293. The conduct of Pharmacy Defendants, their agents, and their employees is, at the very least, negligent.

D. Defendants' Misconduct Has Damaged the Nation and Its Citizens

294. Defendants' misleading marketing and failure to prevent prescription opioid diversion damaged the Nation and its citizens. Defendants' misconduct has contributed to a range of social problems, including violence and delinquency. Adverse social outcomes include child neglect, family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more of the Nation's resources are devoted to addiction-related problems. Meanwhile, the opioid crisis diminishes the Nation's available workforce, decreases productivity, increases poverty, and consequently requires greater expenditures by the Nation.

VII. FACTS PERTAINING TO CLAIMS UNDER RICO

295. Defendants did not simply scheme to market opioids through misrepresentations and turning a blind eye to diversion. Various groups of Defendants also formed informal associations with others ("Enterprises") and used these Enterprises to perpetrate their schemes, as described below.

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

296. Knowing that their name-brand and generic prescription opioids were highly addictive, ineffective, and unsafe for the treatment of long-term, chronic pain, non-acute, and non-cancer pain, the Marketing Manufacturer Defendants formed an association-in-fact enterprise with the Front Groups and KOLs described above (the "Opioid Marketing Enterprise"). The Marketing Manufacturer Defendants used this Enterprise to engage in a scheme to increase their profits and sales unlawfully, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term, chronic pain.

297. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The Marketing Manufacturer Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioid-friendly messaging, fueled the opioid epidemic in the United States.[138]

[138] *See Fueling an Epidemic*, *supra* note 125, https://www.hsdl.org/?abstract&did=808171.

298. The Marketing Manufacturer Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including the Nation, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included the following: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Marketing Manufacturer Defendants named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse. The misleading statements not only caused and worsened the opioid epidemic, but as time went on, they concealed the Marketing Manufacturer Defendants' wrongdoing from the public and the Nation (including as a result of the Opioid Marketing Enterprise).

299. The scheme devised, implemented, and conducted by the Marketing Manufacturer Defendants constituted a common course of conduct designed to ensure that the Marketing Manufacturer Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effectiveness of their drugs. The Marketing Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetrated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

300. There was regular communication among the Marketing Manufacturer Defendants, Front Groups, and KOLs, in which information was shared, misrepresentations were coordinated, and payments were exchanged. Typically, the coordination, communication, and payment occurred, and continues to occur, through the repeated and continuing use of interstate wires and mail in which the Marketing Manufacturer Defendants, Front Groups, and KOLs shared information regarding overcoming objections and resistance to the use of opioids for chronic pain. The Marketing Manufacturer Defendants, Front Groups, and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence. These actions were effective to conceal the scheme and the Opioid Marketing Enterprise and its impact from the Nation until sufficient information came to light due to government and media investigation to allow the Nation to discover it, leading to the filing of the Complaint in this matter.

301. At all relevant times, the Front Groups were aware of the Marketing Manufacturer Defendants' conduct and were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Nation. But for the Opioid Marketing Enterprise's scheme, the Front Groups would have had incentive to disclose the deceit by the Marketing Manufacturer Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, continued its wrongful concealment from the Nation, and reaped substantial benefits.

302. At all relevant times, the KOLs were aware of the Marketing Manufacturer Defendants' conduct and were knowing and willing participants in and beneficiaries of that conduct. The Marketing Manufacturer Defendants selected KOLs because they favored the aggressive treatment of chronic pain with opioids. The Marketing Manufacturer Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely promoted the benefits of using opioids to treat chronic pain, repaying the Marketing Manufacturer Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Nation. But for the Opioid Marketing Enterprise's scheme, the KOLs would have had incentive to disclose the deceit by the Marketing Manufacturer Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, the KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, continued its wrongful concealment from the Nation, and reaped substantial benefits.

303. As public scrutiny and media coverage focused on how opioids ravaged communities throughout the United States, the Front Groups and KOLs did not challenge the Marketing Manufacturer Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and that the use of opioids for chronic pain was not supported by medically acceptable evidence. The Marketing Manufacturer Defendants and their co-conspirators thus continued to conceal the Marketing Manufacturer Defendants' wrongdoing from the Nation.

2. The Conduct of the Opioid Marketing Enterprise

304. The Marketing Manufacturer Defendants, Front Groups, and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. The conduct of the members of the Opioid Marketing Enterprise in furtherance of the Enterprise's common purpose involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term, chronic pain (described in detail above); (2) efforts to criticize or undermine the CDC Guideline referenced above;[139] and (3) efforts to limit prescriber accountability.

305. In addition to disseminating misrepresentations about the risks and benefits of opioids, members of the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining the CDC Guideline, which represented "an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."[140]

306. Several Front Groups, including the U.S. Pain Foundation and the American Academy of Pain Medicine ("AAPM"), criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to

[139] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[140] Staff of S. Comm. on Homeland Sec. & Governmental Affairs, 115th Cong., Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups (Comm. Print 2018), https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (last checked on May 22, 2018).

disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."[141]

307. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."[142]

308. The Marketing Manufacturer Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the Marketing Manufacturer Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

309. The impact of the Opioid Marketing Enterprise's scheme is still impacting the Nation—i.e., opioids continue to be prescribed and used for chronic pain throughout the area of the Nation's territory, and the epidemic continues to injure the Nation, and consume its resources, including the Nation's healthcare, criminal justice, social services, welfare, and education systems.

310. In short, the Marketing Manufacturer Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose

[141] Am. Acad. of Pain Medicine, CDC Guideline for Prescribing Opioids for Chronic Pain (Mar. 16, 2016), http://www.painmed.org/files/aapm-statement-cdc-guideline-for-prescribing-opioids-for-chronic-pain.pdf.

[142] Pat Anson, *Chronic Pain Groups Blast CDC for Opioid Guidelines*, Pain News Network, Sept. 22, 2015, https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines.

and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

311. From approximately the late 1990s to the present, each of the Marketing Manufacturer Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of its affairs, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading, and unsupported medical and popular literature, electronic and print advertisements, sales and promotional training materials, and presentations about opioids that: (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) were thus more likely to be relied upon by physicians, patients, and payors;

b. Selecting, cultivating, promoting, and paying Front Groups and KOLs based on their willingness to communicate and distribute the Marketing Manufacturer Defendants' messages about the use of opioids for chronic pain;

c. Providing substantial opportunities for Front Groups and KOLs to participate in research studies on topics the Marketing Manufacturer Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. Paying KOLs to serve as consultants or on the Marketing Manufacturer Defendants' advisory boards, or on the advisory boards and in leadership positions of Front Groups, and to give talks, typically over meals or at conferences;

e. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

f. Donating to Front Groups to support talks that were typically presented over meals or at conferences;

g. Disseminating false, misleading, imbalanced, and unsupported statements regarding opioids through unbranded materials that appeared to be independent publications from Front Groups;

h. Sponsoring programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

i. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and Front Groups as publishers and supporters;

j. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the Marketing Manufacturer Defendants, such as veterans and the elderly, and then funding that distribution;

k. Concealing their relationship to and control of Front Groups and KOLs from the Nation and the public at large; and

l. Intending that Front Groups and KOLs would distribute, through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

312. The Marketing Manufacturer Defendants controlled representations made about their prescription opioids, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the Marketing Manufacturer Defendants' sales detailers were consistent with the Marketing Manufacturer Defendants' messaging throughout the United States. The Front Groups and KOLs in the Opioid Marketing Enterprise were dependent on the Marketing Manufacturer Defendants for their financial structure and for career development and promotion opportunities.

313. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the Marketing Manufacturer Defendants' drugs that were consistent with the Marketing Manufacturer Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials that claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Marketing Manufacturer Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 CDC Guideline, which had recommended limits on opioid prescriptions for chronic pain;[143] and

f. The Front Groups concealed their connections to the KOLs and the Marketing Manufacturer Defendants.

314. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the Marketing Manufacturer Defendants' drugs that were consistent with the Marketing Manufacturer Defendants' messages;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials that claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Marketing Manufacturer Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 CDC Guideline, which had recommended limits on opioid prescriptions for chronic pain;[144] and

f. The KOLs concealed their connections to the Front Groups and the Marketing Manufacturer Defendants, and their sponsorship by the Marketing Manufacturer Defendants.

315. The scheme devised and implemented by the Marketing Manufacturer Defendants and members of the Opioid Marketing Enterprise amounted to a common course of conduct

[143] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
[144] *Id.*

intended to increase the Marketing Manufacturer Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term, chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue to the present.

316. As discussed above, the Marketing Manufacturer Defendants funded and controlled the various Front Groups. The Front Groups, which appeared to be independent, but were not, transmitted the Marketing Manufacturer Defendants' misrepresentations. The Marketing Manufacturer Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

317. The Marketing Manufacturer Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

318. Similarly, as discussed above, the Marketing Manufacturer Defendants paid KOLs, including Dr. Portenoy, to spread their misrepresentations and promote their products. The Marketing Manufacturer Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

3. The Pattern of Racketeering Activity

319. The Marketing Manufacturer Defendants' scheme was perpetrated through multiple acts of mail fraud and wire fraud that constituted a pattern of racketeering activity.

320. This pattern of racketeering activity involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities, including misrepresentations, concealments, and material omissions regarding the beneficial uses and non-addictive qualities of prescription opioids for the long-term treatment of chronic, non-acute, and non-cancer pain, with the goal of profiting from increased sales of the Marketing Manufacturer Defendants' opioids.

321. Each of these fraudulent mailings and interstate wire transmissions constitutes a separate act of racketeering activity, and collectively, these violations constitute a pattern of racketeering activity.

322. The Marketing Manufacturer Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive, and effective use of opioids for long-term, chronic, non-acute, and non-cancer pain. The Marketing Manufacturer Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA-approved use of these drugs, and were not supported by actual evidence. The Marketing Manufacturer Defendants intended that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to defraud and to advance their illegal scheme.

323. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators, the public, and the Nation, the Marketing Manufacturer Defendants, the Front Groups, and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

324. The Marketing Manufacturer Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the fraudulent marketing of opioids involved thousands of communications, publications, representations, statements, electronic transmissions, and payments, including, *inter alia*:

a. Marketing materials about opioids and their risks and benefits, which Marketing Manufacturer Defendants, Front Groups, and KOLs published and transmitted to healthcare providers located across the country through the Internet and television;

b. Written representations and telephone calls between the Marketing Manufacturer Defendants and Front Groups regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of prescription opioids for chronic long-term pain generally;

c. Written representations and telephone calls between the Marketing Manufacturer Defendants and KOLs regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of prescription opioids for chronic long-term pain generally;

d. E-mails, telephone calls, and written communications between the Marketing Manufacturer Defendants and the Front Groups agreeing to or implementing the scheme for the fraudulent marketing of opioids;

e. E-mails, telephone calls, and written communications between the Marketing Manufacturer Defendants and the KOLs agreeing to or implementing the scheme for the fraudulent marketing of opioids;

f. Communications between the Marketing Manufacturer Defendants, Front Groups, and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g. Communications between the Marketing Manufacturer Defendants, KOLs, and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h. Written and oral communications directed to state agencies, Federal and state courts, and private insurers throughout the country that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits—the wrongful proceeds of the scheme sent through the U.S. Mail and interstate wire facilities.

325. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the Marketing Manufacturer Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those

publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

326. The Marketing Manufacturer Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the Marketing Manufacturer Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud in marketing prescription opioids.

327. Indeed, for the Marketing Manufacturer Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the Marketing Manufacturer Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, presentations, and prescription guidelines.

328. The Marketing Manufacturer Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured the Nation's business and property, while simultaneously generating billion-dollar revenue and profits for the Marketing Manufacturer Defendants. The predicate acts were committed or caused to be committed by the Marketing Manufacturer Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

B. The Opioid Supply Chain Enterprise

1. The Common Purpose and Scheme of the Opioid Supply Chain Enterprise

329. In addition to the Opioid Marketing Enterprise, there existed a second, separate enterprise. For more than a decade, Defendants worked together in an illicit enterprise, engaging in illegal conduct with the common purpose and achievement of vastly increasing their

respective profits and revenues by exponentially expanding a market that the law intended to restrict (the "Opioid Supply Chain Enterprise").

330. Through the connections they made as a result of their participation in HDA, Defendants chose to flout the closed system designed to protect citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention of Diversion of Controlled Substances." But, privately, Defendants refused to act. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the had, said to Congress in 2014, it is "difficult to find the balance between proactive and anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications."[145] Yet, Defendants apparently all found the same profit-maximizing balance—intentionally remaining silent to ensure the largest possible financial return.

331. Defendants thereby breached their duties under the FCSA. As "registrants" under the FCSA, Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[146] Critically, Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when Defendants obtain information about the sales and distribution of other companies' prescription

[145] *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 113th Cong. (2014) (statement of John Gray), https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg90872/html/CHRG-113hhrg90872.htm.
[146] 21 C.F.R. § 1301.74(b).

opioid products (including both name-brand prescription opioids and their generic equivalents), as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

332. At all relevant times, Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by fraudulently increasing the quotas set by the DEA that would allow them to benefit collectively from a greater pool of prescription opioids. In support of this common purpose and fraudulent scheme, Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market. Their collective silence in the face of their duties to speak constituted concealment of their wrongdoing that effectively kept it hidden from the public and the Nation until government and media investigation revealed sufficient information to bring their wrongful conduct causing the opioid epidemic to light, leading to the Complaint in this matter.

2. The Conduct of the Opioid Supply Chain Enterprise

333. At all relevant times, Defendants exerted control over, conducted, and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties to identify, investigate, and report suspicious orders of opioids.

334. Defendants disseminated false and misleading statements to Federal and state regulators claiming that:

a. the quotas for prescription opioids should be increased; and

b. they were complying with their obligations to: (i) maintain effective controls against diversion of their prescription opioids; (ii) design and operate a system to disclose suspicious orders of prescription opioids; and (iii) notify the DEA of any suspicious orders or diversion of their prescription opioids.

335. The FCSA and the Code of Federal Regulations require Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the FCSA and Code of Federal Regulations amounts to a criminal violation of the statute. It also constitutes concealment of Diversion Defendants' wrongful fulfillment of suspicious orders.

336. Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records, and other documents required to be filed with the DEA, including the Marketing Manufacturer Defendants' and Diversion Manufacturer Defendants' applications for production quotas. Specifically, Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

3. The Pattern of Racketeering Activity

337. Defendants used, directed the use of, and/or caused to be used, thousands of mail and interstate wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

338. Defendants devised and knowingly carried out a scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts when there was a duty to disclose.

339. For the purpose of executing the illegal scheme, Defendants used the mail and interstate wires intentionally and knowingly with the specific intent to defraud and advance the illegal scheme. These repeated acts of mail fraud and wire fraud constituted a pattern of racketeering activities.

340. Defendants' use of the mail and interstate wires included, but was not limited to, the transmission, delivery, or shipment of the following by Defendants, or third parties that foreseeably sent them as a result of Defendants' illegal scheme:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase, and sale of prescription opioids;

d. Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

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

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributor Defendants to the Marketing Manufacturer Defendants;

k. Rebates and chargebacks from the Marketing Manufacturer Defendants and the Diversion Manufacturer Defendants to the Distributor Defendants;

l. Payments to the Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

m. Deposits of proceeds from the Defendants' manufacture, distribution, and sale of prescription opioids; and

n. Other documents and things, including electronic communications.

341. Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

342. Defendants used the Internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and state laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

343. At the same time, Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all Federal and state regulations regarding the identification and reporting of suspicious orders of prescription opioids.

344. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators, the public, and the Nation into believing that Defendants were complying with their Federal and state obligations to identify and report suspicious orders of prescription opioids while Defendants were knowingly allowing millions of doses of prescription opioids to be diverted into the illicit drug market.

Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

345. Many of the precise dates of the uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, the Nation has described the types of and, in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetrate and maintain the scheme, including the things and documents described in the preceding paragraphs.

346. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

347. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured the Nation's business and property, as well as the health and welfare of the Nation's citizens, while simultaneously generating billion-dollar revenue and profits for Defendants. The predicate acts were committed or caused to be committed by Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

348. As described above, Defendants were repeatedly warned, fined, and found to be in violation of applicable laws and regulations, and yet they persisted. The sheer volume of enforcement actions against Defendants supports this conclusion that Defendants operated

through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.147

349. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

C. Effects of the Opioid Marketing Enterprise and the Opioid Supply Chain Enterprise

350. The Nation's injuries were proximately caused by Defendants' racketeering activity, which directly caused the over-prescription, over-purchase, and over-consumption of name-brand prescription opioids and their generic equivalents. But for Defendants' misstatements and omissions and the schemes employed by the Opioid Marketing Enterprise and the Opioid Supply Chain Enterprise, the Nation would not have paid for opioid prescriptions for chronic pain and would not be bearing the costs of its current opioid epidemic.

351. By reason of, and as a result of the conduct of each of the Defendants, and in particular, their pattern of racketeering activity, the Nation has been injured in its business and property in multiple ways, including, but not limited to, suffering increased law enforcement and public works expenditures, increased emergency and treatment services, damage to emergency equipment and vehicles, the processing and payment of fraudulent prescriptions, other increased medical costs, and lost productivity, economic opportunity, and tax revenue. The health and welfare of the Nation's citizens also has been injured.

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

352. Defendants' violations of 18 U.S.C. § 1962(c) have directly and proximately caused injuries and damages to the Nation, and the Nation is entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

CLAIMS FOR RELIEF

COUNT I

VIOLATION OF RICO, 18 U.S.C. § 1961 *et seq*.
OPIOID MARKETING ENTERPRISE
(Against the Marketing Manufacturer Defendants)

353. The Nation incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

354. At all relevant times, the Marketing Manufacturer Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

355. The Opioid Marketing Enterprise was an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4) consisting of the Marketing Manufacturer Defendants, the Front Groups, and the KOLs. The activities of this Enterprise affected interstate commerce.

356. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each member of the Opioid Marketing Enterprise; (b) was separate and distinct from the pattern of racketeering in which the Marketing Manufacturer Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Marketing Manufacturer Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the Marketing Manufacturer Defendants and each of the Front

Groups and KOLs; (e) had sufficient longevity for the Opioid Marketing Enterprise to pursue its purpose; and (f) functioned as a continuing unit.

357. In particular, each of the Marketing Manufacturer Defendants, KOLs, and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through (a) joint participation in lobbying groups, (b) trade industry organizations, (c) contractual relationships, and (d) continuing coordination of activities. These systematic links and personal relationships allowed members of the Opioid Marketing Enterprise to act with a common purpose and to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the Marketing Manufacturer Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry-friendly and would work together with the Marketing Manufacturer Defendants to advance the common purpose of the Opioid Marketing Enterprise.

358. Each of the Marketing Manufacturer Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a role in furthering the Enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use.

359. Specifically, the Marketing Manufacturer Defendants: (1) through the use of Front Groups that appeared to be independent of the Marketing Manufacturer Defendants; (2) through the dissemination of publications that supported the Marketing Manufacturer Defendants' scheme; (3) through continuing medical education ("CME") programs controlled and/or funded by the Marketing Manufacturer Defendants; (4) by the hiring and deployment of

so-called KOLs who were paid by the Marketing Manufacturer Defendants to promote their message; and (5) through the "detailing" activities of the Marketing Manufacturer Defendants' sales forces conducted an association-in-fact enterprise, and/or participated in the conduct of that enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry out the common purpose of the Opioid Marketing Enterprise. The Opioid Marketing Enterprise sought to further this common purpose through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use. In so doing, each of the Marketing Manufacturer Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise by engaging in mail and wire fraud in violation of 18 U.S.C. § 1962(c).

360. Together with the Fronts Groups and KOLs, the Marketing Manufacturer Defendants formed an association-in-fact enterprise, the Opioid Marketing Enterprise, for the purpose of increasing unlawful profits and revenues from the continued prescription and use of name-brand prescription opioids and their generic equivalents for long-term, chronic pain and through creating widespread dependency on and addiction to opioids.

361. The Marketing Manufacturer Defendants each worked together to coordinate the Opioid Marketing Enterprise's goals and conceal their role, and the Opioid Marketing Enterprise's existence, from the public by, among other things: (i) funding, editing, and distributing publications that supported and advanced their false messages; (ii) funding KOLs to promote their false messages; (iii) funding, editing, and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (that is, sales detailing).

362. Each of the Front Groups helped disguise the role of the Marketing Manufacturer Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials—a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the Marketing Manufacturer Defendants' false messages.

363. Each of the KOLs was a physician chosen and paid by one or more of the Marketing Manufacturer Defendants to influence prescribers' habits by promoting the Marketing Manufacturer Defendants' false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the Marketing Manufacturer Defendants' role in the Opioid Marketing Enterprise and the Opioid Marketing Enterprise's existence.

364. The Marketing Manufacturer Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(5) that employed the use of mail and interstate wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids.

365. The Marketing Manufacturer Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud.

366. Indeed, for the Marketing Manufacturer Defendants' fraudulent scheme to work, each of the Marketing Manufacturer Defendants had to agree to implement similar tactics.

367. The Marketing Manufacturer Defendants' predicate acts of racketeering activity (18 U.S.C. § 1961(1)) consisted of:

a. Mail Fraud: The Marketing Manufacturer Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

b. Wire Fraud: The Marketing Manufacturer Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by interstate wires for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

368. Each of the Marketing Manufacturer Defendants not only violated the above laws but also aided and abetted others in the violations of the above laws, thereby rendering the Marketing Manufacturer Defendants indictable as principals.

369. As summarized herein, the Marketing Manufacturer Defendants used the mail and interstate wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions, and payments to carry out the Opioid Marketing Enterprise's fraudulent scheme.

370. Because the Marketing Manufacturer Defendants disguised their participation in the Opioid Marketing Enterprise, and worked to keep even the Opioid Marketing Enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the Marketing Manufacturer Defendants, Front Groups, and KOLs. Indeed, an

essential part of the successful operation of the Opioid Marketing Enterprise depended upon secrecy. However, the Nation has described occasions on which the Marketing Manufacturer Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to consumers, prescribers, regulators, and the Nation, and how those acts were in furtherance of the scheme.

371. The Marketing Manufacturer Defendants each committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Marketing Manufacturer Defendants committed, conspired to commit, and/or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity and/or constituted continuous racketeering activity, and therefore constituted a "pattern of racketeering activity." The racketeering activity was made possible by the Marketing Manufacturer Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise. The Marketing Manufacturer Defendants participated in the scheme to defraud by using mail and interstate wires (including telephones and the Internet) in interstate or foreign commerce.

372. As described herein, the Marketing Manufacturer Defendants engaged in a pattern of related and continuous acts for years. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators, and the Nation.

373. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs.

374. The Marketing Manufacturer Defendants, Front Groups, and KOLs intentionally crafted their fraudulent scheme in accordance with the common purpose of the Opioid Marketing Enterprise to ensure that their own profits—and the rewards of the scheme meted out to the Front Groups and KOLs—remained high. In designing and implementing the scheme, the Marketing Manufacturer Defendants understood and intended that those in the distribution chain would rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the Marketing Manufacturer Defendants' products.

375. The racketeering activities conducted by the Marketing Manufacturer Defendants, Front Groups, and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive consumers, prescribers, regulators, and the Nation. The Marketing Manufacturer Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing affairs of the Opioid Marketing Enterprise.

376. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

377. The Marketing Manufacturer Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the Nation injury in its business and property. They also directly and proximately caused injury to the Nation's citizens. The Marketing Manufacturer Defendants' pattern of racketeering activity logically, substantially, and

foreseeably caused an opioid epidemic. The Nation's injuries were not unexpected, unforeseen, or independent. Rather, as the Nation alleges, the Marketing Manufacturer Defendants knew that the opioids were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the Marketing Manufacturer Defendants engaged in a scheme that utilized the mail and interstate wires in order to carry out the Opioid Marketing Enterprise's fraudulent scheme, thereby increasing sales of their opioid products.

378. Specifically, the Marketing Manufacturer Defendants' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry out their fraudulent scheme has injured the Nation in the form of substantial losses of money and property that logically, directly, and foreseeably arose from the opioid epidemic. The health and welfare of the Nation's citizens also have been injured. The Nation's injuries, as alleged throughout this Complaint, are hereby expressly incorporated herein by reference.

379. The Nation is most directly harmed and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

COUNT II

VIOLATION OF RICO, 18 U.S.C. § 1961 *et seq*.
OPIOID SUPPLY CHAIN ENTERPRISE
(Against All Defendants)

380. The Nation incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

381. At all relevant times, the Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

382. The Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States, including but not limited to creating a market for non-medical use of opioids of epidemic proportions. The Opioid Supply Chain Enterprise was an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4) consisting of the Defendants. The activities of the Opioid Supply Chain Enterprise affected interstate commerce.

383. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each member of the Opioid Supply Chain Enterprise; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Supply Chain Enterprise, i.e., the Defendants; (e) had sufficient longevity for the Opioid Supply Chain Enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the Enterprise through a pattern of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and the resulting sales.

384. Many of the Defendants are members, participants, and/or sponsors of the HDA, and have been since at least 2006, and utilized the HDA to form the systematic links and interpersonal relationships of the Opioid Supply Chain Enterprise and to assist the Defendants in engaging in the pattern of racketeering activity that gives rise to this Count.

385. The Defendants conducted and participated in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(5).

386. The pattern of racketeering activity of the Opioid Supply Chain Enterprise included the use of mail and interstate wire facilities, in furtherance of a scheme to defraud Federal and state regulators, the American public, and the Nation in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

387. The pattern of racketeering activity of the Opioid Supply Chain Enterprise also included the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under the laws of the United States.

388. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person knowingly or intentionally to furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of 21 U.S.C. § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1). The Defendants violated 21 U.S.C. § 843(a)(4) by knowingly and intentionally furnishing false information in, and omitting material information from, reports, records, and other documents required to be made, kept, and filed under the relevant subchapter of Title 21 of the United States Code.

389. The pattern of racketeering activity of the Opioid Supply Chain Enterprise also included violations of the Travel Act, 18 U.S.C. § 1952. Defendants violated 18 U.S.C. § 1952 in that they used the mail and facilities in interstate commerce (i.e., interstate wires) with the intent to carry on, or facilitate the carrying on of, an "unlawful activity" within the meaning of

18 U.S.C. § 1952(b), namely, a business enterprise involving controlled substances, and thereafter carried on such unlawful activity, in violation of the laws of the State of Oklahoma. Specifically, the unlawful activity violated 63 Okl. Stat. § 2-406(A)(4), which makes it unlawful "[t]o furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this act, or any record required to be kept by this act . . . ." Such activity also violated 63 Okl. Stat. § 2-401(A)(1), which makes it unlawful to distribute or dispense a controlled substance except as authorized by state law, which would include the Oklahoma Uniform Controlled Dangerous Substances Act and implementing regulations. By turning a blind eye to diversion, Defendants aided and abetted the unlawful distribution and dispensing of prescription opioids, in violation of 63 Okl. Stat. § 2-401(A)(1).

390. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud.

391. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics.

392. In sum, the Defendants' predicate acts of racketeering activity (18 U.S.C. § 1961(1)) consisted of:

a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

b. Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by interstate wire for the purpose of executing the unlawful scheme to

design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, false promises, and omissions.

c. Controlled Substance Violations: The Defendants who are Distributor Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

d. Travel Act Violations: The Defendants violated 18 U.S.C. § 1952 by using the mail and facilities in interstate commerce with the intent to carry on, or facilitate the carrying on of, an unlawful activity, namely, a business enterprise involving controlled substances in violation of Oklahoma law, including Oklahoma law regarding controlled substances and 15 Okla. Stat. § 761.1(E), the criminal provision of the Oklahoma Consumer Protection Act.[148]

393. Each of the Defendants not only violated the above laws but aided and abetted others in the violations of the above laws, thereby rendering Defendants indictable as principals.

394. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

395. The Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the reality of the suspicious orders that the Defendants were filling on a daily basis—leading to the diversion of hundreds of millions of doses of name-brand and generic prescription opioids into the illicit market.

[148] The Nation acknowledges that on December 6, 2017, the district court for Cleveland County, Oklahoma, dismissed the state of Oklahoma's claim against opioid manufacturers under the Consumer Protection Act, but the Nation respectfully disagrees and wishes to preserve the § 761.1(E) argument.

396. The Defendants committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity within the past ten years.

397. The multiple acts of racketeering activity that the Defendants committed, conspired to commit, and/or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity and/or constituted continuous racketeering activity, and therefore constituted a "pattern of racketeering activity." The racketeering activity was made possible by the Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise.

398. As described herein, the Defendants engaged in a pattern of related and continuous predicate acts for years. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators, and the Nation. The predicate acts consisted of a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the distribution and sale of their highly addictive and dangerous drugs. The predicate acts were not isolated or sporadic events.

399. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured the Nation's business and property, as well as the health and welfare of the Nation's citizens, while simultaneously generating billion-dollar revenue and profits for the Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

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

401. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

402. It was foreseeable to the Defendants that the Nation would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the FCSA and Code of Federal Regulations allowed the widespread diversion of name-brand and generic prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic that the FCSA intended to prevent.

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

404. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the Nation's injury in its business and property. The Defendants' pattern of racketeering activity, including their refusal to identify, report, and halt suspicious orders of controlled substances, logically, substantially, and foreseeably caused an opioid epidemic. The Nation was injured and continues to be injured by the Defendants' pattern of racketeering activity and the opioid epidemic that it created.

405. Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, in order to increase sales of their opioid products, the Defendants engaged in a

scheme of deception by refusing to identify or report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the market of non-medical use. They did so by utilizing the mail and interstate wires as part of their fraud.

406. The Defendants' predicate acts and pattern of racketeering activity were a proximate cause of the opioid epidemic that has injured the Nation in the form of substantial losses of money and property that logically, directly, and foreseeably arise from the opioid epidemic brought on by the Defendants' acts. The Defendants' predicate acts also injured the health and welfare of the Nation's citizens.

407. Specifically, the predicate acts and pattern of racketeering activity proximately caused the Nation's injuries, as alleged throughout this Complaint, and such allegations are expressly incorporated herein by reference.

408. The Nation is most directly harmed and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

COUNT III

LANHAM ACT
(Against All Defendants)

409. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

410. The Lanham Act provides, in pertinent part:

> (1) Any person who, on or in connection with any goods or services . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which –
>
> . . .
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics [or] qualities . . . of his or her or another person's goods, services,

> or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

411. As alleged in this Complaint, Defendants, in connection with their manufacture, distribution, and/or sale of prescription opioids, made numerous false or misleading descriptions and representations of fact during the advertising and promotion of prescription opioids.

412. These false or misleading descriptions and representations of fact misrepresented the nature, characteristics, or qualities of the prescription opioids.

413. Specifically, as described herein, Marketing Manufacturer Defendants misrepresented the safety and efficacy of prescription opioids. Diversion Defendants misleadingly represented that they were taking effective steps to prevent diversion.

414. The Nation was damaged by Defendants' false or misleading descriptions and representations of fact.

415. For instance, Marketing Manufacturer Defendants' false or misleading descriptions and representations of fact diverted patients from hospitals and clinics run by the Nation, instead seeking care from doctors and clinics who prescribed high dosages of opioids, which prescriptions in turn were filled with name-brand prescription opioids or their generic equivalents, and whose high-dose prescriptions created incentives for the diversion that Diversion Defendants were not, in fact, taking steps to prevent.

416. But for Marketing Manufacturer Defendants' false advertising as to the safety of opioid drugs, these patients would have sought alternative, safer forms of treatment offered by the Nation's hospitals and clinics. But for Diversion Defendants' false statements regarding their prevention of diversion, these patients would not have sought treatment from doctors and clinics who prescribed high dosages of opioids because they would not have been able to obtain excessive and unnecessary quantities of opioids as a result of their treatment.

417. As alleged herein, and incorporated into this count, the Defendants engaged in systemic false and misleading advertising, via print advertising, promotional materials, and other items designed to deceive doctors and the public into believing that opioids were safe for the treatment of chronic pain. Defendants also designed their systemic false and misleading advertising to reach consumers.

418. The Nation is entitled to legal and equitable relief, including injunctive relief, disgorgement, and damages in an amount to be determined.

COUNT IV

NUISANCE
(Against Marketing Manufacturer Defendants)

419. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

420. Marketing Manufacturer Defendants have caused, are causing, and will continue to cause a public nuisance, in that they have committed offenses against the public order and economy of the Nation by unlawfully marketing prescription opioids through misleading statements in ways that facilitate the sale, distribution, and dispensing of such drugs, including both name-brand prescription opioids and their generic equivalents, from premises on and around the Nation to unauthorized users in the Nation—including children, people at risk of overdose or suicide, and criminals.

421. Marketing Manufacturer Defendants' activities have unreasonably interfered, are interfering, and will interfere with the common rights of the general public:

a. to be free from reasonable apprehension of danger to person and property;

b. to be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread illegal opioid use;

c. to be free from the negative health and safety effects of widespread illegal drug sales on premises on and around the Nation;

d. to be free from blights on the community created by areas of illegal drug use and opioid sales;

e. to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions; and

f. to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

422. Marketing Manufacturer Defendants' interference with these public rights has been, is, and will continue to be unreasonable and objectionable because it:

a. has harmed and will continue to harm the public health and public peace of the Nation;

b. has harmed and will continue to harm the Nation's neighborhoods and communities by increasing crime, and thereby interfering with the rights of the community at large;

c. violates statutory and common law duties;

d. is of a continuing nature, and has produced long-lasting effects; and

e. is known to Marketing Manufacturer Defendants that their conduct has a significant effect upon the public rights of the Nation and its citizens.

423. In addition and independently, the Marketing Manufacturer Defendants' conduct invades a legally protected interest. Marketing Manufacturer Defendants' conduct constitutes an unreasonable, intentional, and substantial interference because, *inter alia*, each Marketing Manufacturer Defendant has conducted a fraudulent campaign to misrepresent knowingly the safety and efficacy of opioid drugs and to ensure their widespread use for chronic pain.

424. Because Marketing Manufacturer Defendants have marketed and sold prescription opioids in a manner contrary to law and because Marketing Manufacturer Defendants' conduct

has unreasonably, intentionally, and substantially interfered with a right common to the general public, Marketing Manufacturer Defendants are liable for public nuisance.

425. The nuisance has affected the Nation in that it has undermined, is undermining, and will continue to undermine the public health, quality of life, and safety of the Nation's citizens. It has resulted in increased crime and property damage within the Nation. It has resulted in high rates of addiction, overdoses, and dysfunction within the Nation's families and communities.

426. The Nation's resources have been, are being, and will be consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the Nation.

427. The Marketing Manufacturer Defendants' actions and omissions annoy, injure, and endanger the comfort, repose, health, and safety of the Nation, offend decency, and render the Nation's citizens insecure in their lives and the use of property.

428. Marketing Manufacturer Defendants' nuisance-causing activities are not outweighed by their utility. In fact, these activities are illegal and have no social utility whatsoever. There is no legitimately-recognized societal interest in marketing and selling prescription opioids through false and misleading representations.

429. At all times, Marketing Manufacturer Defendants possessed the right and ability to control the nuisance-causing flow of name-brand prescription opioids and their generic equivalents into the Nation.

430. As a direct and proximate result of the Marketing Manufacturer Defendants' nuisance, the Nation's citizens have been injured in their ability to enjoy rights common to the public.

431. As a direct and proximate result of the nuisance, the Nation has sustained economic harm by spending substantial sums on the societal harms caused by Marketing Manufacturer Defendants' nuisance-causing activity, including costs to the healthcare, criminal justice, social services, welfare, and education systems.

432. The Nation has also suffered unique harms of a kind that are different from its citizens at large, namely, that the Nation has been harmed in its proprietary interests.

COUNT V

NEGLIGENCE AND NEGLIGENCE PER SE
(Against Marketing Manufacturer Defendants)

433. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

434. Marketing Manufacturer Defendants owe a duty to the Nation to act reasonably under the circumstances.

435. Marketing Manufacturer Defendants also have duties under Federal and Oklahoma law, including the FDCA, to exercise reasonable care in marketing and selling opioids. Those laws seek, among other things, to protect the Nation and its citizens.

436. The conduct of Marketing Manufacturer Defendants has fallen below the reasonable standard of care. Their negligent acts have included the following:

a. marketing opioids with misleading statements resulting in oversupply on and around the Nation of highly addictive prescription opioids;

b. enhancing the risk of harm from prescription opioids by marketing those drugs with misleading statements and omissions;

c. inviting criminal activity into the Nation by marketing prescription opioids in violation of applicable laws and regulations;

d. failing to adhere to all applicable laws and regulations pertaining to the marketing of prescription opioids;

e. failing to train or investigate their employees properly; and

f. failing to provide adequate safeguards against misleading marketing.

437. Each Marketing Manufacturer Defendant had a responsibility to exercise reasonable care in marketing prescription opioids.

438. Each Marketing Manufacturer Defendant marketed prescription opioids using misleading statements and omissions knowing that (a) there was a substantial likelihood this marketing would lead to sales of name-brand prescription opioids and their generic equivalents for illicit or non-medical purposes, and (b) opioids are inherently dangerous when used for chronic pain and non-medical purposes.

439. Marketing Manufacturer Defendants were negligent or reckless in not acquiring or not utilizing special knowledge and special skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such distinctive and significant dangers.

440. Each Marketing Manufacturer Defendant breached its duty to exercise the degree of care commensurate with the dangers involved in marketing and introducing into commerce dangerous controlled substances.

441. Marketing Manufacturer Defendants were also negligent or reckless in voluntarily undertaking duties to the Nation that they breached. Marketing Manufacturer Defendants, through their affirmative statements regarding protecting consumers, undertook duties to take all reasonable precautions to avoid misleading marketing statements.

442. Marketing Manufacturer Defendants were also negligent per se by virtue of having violated laws and regulations pertaining to the marketing of prescription opioids.

443. Marketing Manufacturer Defendants' conduct was the cause-in-fact and proximate cause of injuries and damages to the Nation, including but not limited to the

following: increased costs for the healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenues.

444. The Nation is without fault, and its injuries would not have happened had Marketing Manufacturer Defendants used due care.

445. The reckless, wanton, and reprehensible nature of Marketing Manufacturer Defendants' conduct entitles the Nation to an award of punitive damages and attorneys' fees and costs.

COUNT VI

UNJUST ENRICHMENT
(Against Marketing Manufacturer Defendants)

446. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

447. The Nation has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Marketing Manufacturer Defendants' misleading statements.

448. These expenditures by the Nation have added to Marketing Manufacturer Defendants' wealth and have helped sustain Marketing Manufacturer Defendants' businesses.

449. In this way, the Nation has conferred a benefit upon Marketing Manufacturer Defendants, by paying for what may be called their externalities—the costs of the harm caused by their misleading statements and omissions.

450. Marketing Manufacturer Defendants made substantial profits from their manufacture, marketing, sale, and distribution of their name-brand prescription opioids and, where applicable, their generic equivalents, while fueling the opioid epidemic in the Nation. Marketing Manufacturer Defendants continue to receive considerable profits from the sale of

controlled substances in the Nation. Marketing Manufacturer Defendants are aware of these obvious benefits, and retention of these benefits is unjust. Marketing Manufacturer Defendants have been unjustly enriched by these benefits. It would be inequitable to allow Marketing Manufacturer Defendants to retain these benefits.

COUNT VII

NUISANCE
(Against Diversion Defendants)

451. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

452. Diversion Defendants have caused, are causing, and will continue to cause a public nuisance, in that they have committed offenses against the public order and economy of the Nation by unlawfully:

a. facilitating the diversion of prescription opioids by selling, distributing, or dispensing, or facilitating the sale, distribution, or dispensing of, prescription opioids from premises on and around the Nation to unauthorized users—including children, people at risk of overdose or suicide, and criminals;

b. failing to implement effective controls to guard against theft, diversion, and misuse of prescription opioids from legal supply chains;

c. failing to design and operate an adequate system to detect, halt, and report suspicious orders of prescription opioids; and

d. using property for repeated unlawful sales of prescription opioids.

453. Diversion Defendants' activities have unreasonably interfered, are interfering, and will interfere with the common rights of the public:

a. to be free from reasonable apprehension of danger to person and property;

b. to be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread illegal opioid use;

c. to be free from the negative health and safety effects of widespread illegal drug sales on premises on and around the Nation;

d. to be free from blights on the community created by areas of illegal drug use and opioid sales;

e. to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions; and

f. to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

454. Diversion Defendants' interference with these public rights has been, is, and will continue to be unreasonable and objectionable because it:

a. has harmed and will continue to harm the public health and public peace of the Nation;

b. has harmed and will continue to harm the Nation neighborhoods and communities by increasing levels of crime and thereby interfering with the rights of the community at large;

c. is proscribed by Federal laws and regulations;

d. is of a continuing nature, and has produced long-lasting effects; and

e. is known to Distributor and Pharmacy Defendants that their conduct has a significant effect upon the public rights of the Nation and its citizens.

455. In addition and independently, Diversion Defendants' conduct invades a legally protected interest. Diversion Defendants' conduct constitutes an unreasonable, intentional, and substantial interference because, *inter alia*, each Diversion Defendant has permitted dangerous drugs under their control to be diverted for illicit purposes such as to injure the Nation and its citizens.

456. Because Diversion Defendants have marketed and sold prescription opioids in a manner contrary to law and because Diversion Defendants' conduct has unreasonably,

intentionally, and substantially interfered with a right common to the general public, Diversion Defendants are liable for public nuisance.

457. The nuisance has affected the Nation in that it has undermined, is undermining, and will continue to undermine the Nation citizens' public health, quality of life, and safety. It has resulted in increased crime and property damage within the Nation. It has resulted in high rates of addiction, overdoses, and dysfunction within the Nation.

458. Public resources have been, are, and will continue to be consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the Nation public at large.

459. At all times, Diversion Defendants had the obligation and the ability to control the sale, distribution, or dispensing of prescription opioids in the Nation. Diversion Manufacturer Defendants and Distributor Defendants had the power to shut off the illicit supply of name-brand prescription opioids and their generic equivalents into the Nation, and Pharmacy Defendants had the power to prevent the sale of prescription opioids in the Nation for non-medical purposes.

460. Diversion Defendants' actions and omissions annoy, injure and endanger the comfort, repose, health, and safety of the Nation, offend decency, and render the citizens of the Nation insecure in their lives and the use of property.

461. Diversion Defendants' nuisance-causing activities are not outweighed by the utility of Diversion Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately-recognized societal interest in failing to identify, halt, and report suspicious opioid transactions.

462. At all times, Diversion Manufacturer Defendants and Distributor Defendants had the power to shut off the supply of illicit opioids into the Nation, and Diversion Defendants

possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacy locations or other points of sale into the surrounding Nation.

463. As a direct and proximate result of the nuisance, the Nation citizens have been injured in their ability to enjoy rights common to the general public.

464. As a direct and proximate result of the nuisance, the Nation has sustained economic harm by spending substantial sums trying to fix the societal harms caused by Diversion Defendants' nuisance-causing activity, including costs to the healthcare, criminal justice, social services, welfare, and education systems.

COUNT VIII

NEGLIGENCE AND NEGLIGENCE PER SE
(Against Diversion Defendants)

465. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

466. Diversion Defendants owe a duty to act reasonably under the circumstances.

467. Diversion Defendants also have duties under Federal and Oklahoma law, including the FCSA and the Oklahoma CSA, to exercise reasonable care in selling and distributing opioids. Those laws seek, among other things, to protect the Nation and its citizens.

468. The conduct of Diversion Defendants fell below the reasonable standard of care. Their negligent acts include the following:

a. oversupplying the market on and around the Nation with highly-addictive prescription opioids;

b. using unsafe distribution and dispensing practices;

c. enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

d. inviting criminal activity into the Nation by disregarding precautionary measures built into applicable laws and regulations;

e. failing to adhere to all applicable laws and regulations pertaining to the distribution and sale of prescription opioids;

f. failing to train or investigate their employees properly;

g. failing to review prescription orders for red flags;

h. failing to report suspicious orders or refuse to fill them;

i. failing to provide effective controls and procedures to guard against theft and diversion of controlled substances; and

j. failing to police the integrity of the supply chain for prescription opioids.

469. Each Diversion Defendant had a responsibility to control the sale, distribution, or dispensing of prescription opioids.

470. Each Diversion Defendant sold name-brand prescription opioids and, where applicable, their generic equivalents, when it knew or should have known that: (a) there was a substantial likelihood that many of the sales were for non-medical purposes; and (b) opioids are inherently dangerous when used for non-medical purposes.

471. Diversion Defendants were negligent or reckless in not acquiring or not utilizing special knowledge and special skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such distinctive and significant dangers.

472. Diversion Defendants were also negligent or reckless in failing to guard against foreseeable third-party negligence or misconduct, including that of negligent or corrupt prescribers, pharmacists, and staff, and criminals who buy and sell opioids for non-medical purposes.

473. Each Diversion Defendant breached its duty to exercise the degree of care commensurate with the dangers involved in selling dangerous controlled substances.

474. Diversion Defendants were also negligent or reckless in voluntarily undertaking duties to the Nation that they breached. Diversion Defendants, through their statements to the media, regulators, insurance companies, customers, and the public at large, undertook duties to take all reasonable precautions to prevent drug diversion.

475. Diversion Defendants were also negligent per se by virtue of having violated laws and regulations pertaining to the diversion of prescription opioids.

476. Diversion Defendants' conduct was the cause-in-fact and proximate cause of injuries and damages to the Nation, including but not limited to the following: increased costs for the healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenues.

477. The Nation is without fault, and the injuries to it would not have happened in the ordinary course of events if Diversion Defendants had used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

478. The reckless, wanton, and reprehensible nature of Diversion Defendants' conduct entitles the Nation to an award of punitive damages and attorneys' fees and costs.

COUNT IX

UNJUST ENRICHMENT
(Against Diversion Defendants)

479. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

480. The Nation has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Diversion Defendants' conduct.

481. The Nation's expenditures in providing healthcare services to people who use opioids have added to Diversion Defendants' wealth. The expenditures by the Nation have helped sustain Diversion Defendants' businesses.

482. In this way, the Nation has conferred a benefit upon Diversion Defendants, by paying for what may be called Diversion Defendants' externalities—the costs of the harm caused by Diversion Defendants' improper sales, distribution, and dispensing practices.

483. Diversion Defendants made substantial profits from their sale of name-brand prescription opioids and, where applicable, their generic equivalents, while fueling the opioid epidemic in the Nation.

484. Diversion Defendants continue to receive considerable profits from the sale, distribution, and dispensing of controlled substances in the Nation. Diversion Defendants are aware of these obvious benefits, and that retention of these benefits is not justified under these circumstances. Diversion Defendants have been unjustly enriched by these benefits. It would be inequitable to allow Diversion Defendants to retain these benefits.

COUNT X

CIVIL CONSPIRACY
(Against All Defendants)

485. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

486. Marketing Manufacturer Defendants have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids. Their aggressive marketing campaign enabled Marketing Manufacturer Defendants to overcome the longstanding medical consensus that opioids were unsafe for the treatment of

chronic pain and resulted in a significant increase in the number of opioids prescribed nationwide.

487. In response to and in conjunction with this increased demand, Diversion Manufacturer Defendants continuously supplied name-brand prescription opioids and, where applicable, their generic equivalents to Distributor Defendants, which Distributor Defendants then continuously supplied to Pharmacy Defendants, which then dispensed these prescription opioids to consumers, including the Nation's citizens. These transactions occurred despite Diversion Defendants having actual or constructive knowledge that they were habitually breaching their common law duties and violating the FCSA.

488. Without Marketing Manufacturer Defendants' misrepresentations, which created demand, Diversion Defendants would not have been able to sell the increasing number of orders of prescription opioids for non-medical purposes throughout the Nation.

489. Without Diversion Manufacturer Defendants' and Distributor Defendants' supply of prescription opioids, Pharmacy Defendants would not have been able to fill the increasing number of orders of prescription opioids for non-medical purposes throughout the Nation.

490. None of the Defendants would have succeeded in profiting so much from the opioid epidemic without the concerted conduct of the other parties.

491. The Defendants agreed with each other to accomplish the unlawful purposes of marketing, selling, distributing, and retailing prescription opioids through violations of law and misrepresentations. The Defendants performed numerous overt acts in furtherance of this conspiracy, including marketing, selling, distributing, and retailing prescription opioids by means of misrepresentations and omissions, violating Federal and state laws, and turning a blind eye to diversion of prescription opioids.

492. As a result of the concerted action between Marketing Manufacturer Defendants, Diversion Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants, the Nation and its citizens have suffered damages.

493. Defendants are jointly and severally liable for the results of their concerted efforts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the Nation, prays that this Court enter judgment in its favor against Defendants and:

a. On Count I (RICO Violation Against Marketing Manufacturer Defendants):

i. Enter an order awarding the Nation its actual and treble damages stemming from the Marketing Manufacturer Defendants' violations of RICO;

ii. Enter an order for equitable and/or injunctive relief in the form of court-supervised corrective communication, actions, and programs;

iii. Enter an order forfeiting any property acquired or maintained by the Marketing Manufacturer Defendants through their racketeering activity; and

iv. Award the Nation the costs of bringing this action, investigative costs and fees, attorneys' fees, and such other and additional relief as the Court may determine to be just and proper.

b. On Count II (RICO Violation Against All Defendants):

i. Enter an order awarding the Nation its actual and treble damages stemming from the Defendants' violations of RICO;

ii. Enter an order for equitable and/or injunctive relief in the form of court-supervised corrective communication, actions, and programs;

iii. Enter an order forfeiting any property acquired or maintained by the Defendants through their racketeering activity; and

iv. Award the Nation the costs of bringing this action, investigative costs and fees, attorneys' fees, and such other and additional relief as the Court may determine to be just and proper.

c. On Count III (Lanham Act Violation Against All Defendants):

i. Enter an order awarding the Nation its actual damages stemming from Defendants' violations of the Lanham Act; and

ii. Award the Nation the costs of bringing this action, investigative costs and fees, attorneys' fees, and such other and additional relief as the Court may determine to be just and proper.

d. On Count IV (Nuisance Against Marketing Manufacturer Defendants):

i. Order Marketing Manufacturer Defendants to pay the expenses the Nation has incurred or will incur in the future to abate fully the nuisance they have caused;

ii. Award the Nation punitive damages; and

iii. Order such further relief as justice and equity may require.

e. On Count V (Negligence and Negligence Per Se Against Marketing Manufacturer Defendants):

i. Award the Nation compensatory damages for the increased costs to the Nation's healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity due to Marketing Manufacturer Defendants' negligence;

ii. Award the Nation punitive damages;

iii. Award the Nation attorneys' fees and costs; and

iv. Order such further relief as justice and equity may require.

f. On Count VI (Unjust Enrichment Against Marketing Manufacturer Defendants):

i. Award the Nation restitution of its costs caused by Marketing Manufacturer Defendants' actions, including the costs of addressing Defendants' externalities and the costs of prescription opioids paid for by the Nation;

ii. Disgorge Marketing Manufacturer Defendants of all amounts they have unjustly obtained; and

iii. Order such further relief as justice and equity may require.

g. On Count VII (Nuisance Against Diversion Defendants):

i. Order Diversion Defendants to pay the expenses the Nation has incurred or will incur in the future to abate fully the nuisance they have caused;

ii. Award the Nation punitive damages; and

iii. Order such further relief as justice and equity may require.

h. On Count VIII (Negligence And Negligence Per Se Against Diversion Defendants):

i. Award the Nation compensatory damages for the increased costs to the Nation's healthcare, criminal justice system, social services, welfare, and education systems, as well as the cost of lost productivity due to Diversion Defendants' negligence;

ii. Award the Nation punitive damages;

iii. Award the Nation attorneys' fees and costs; and

iv. Order such further relief as justice and equity may require.

i. On Count IX (Unjust Enrichment Against Diversion Defendants):

i. Award the Nation restitution of its costs caused by Diversion Defendants' actions, including the costs of addressing Diversion Defendants' externalities and the costs of prescription opioids paid for by the Nation;

ii. Disgorge Diversion Defendants of all amounts they have unjustly obtained; and

iii. Order such further relief as justice and equity may require.

j. On Count X (Civil Conspiracy Against All Defendants):

i. Award the Nation compensatory and punitive damages for the conspiracy in which Marketing Manufacturer Defendants, Diversion Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants engaged; and

ii. Order such further relief as justice and equity may require.

REQUEST FOR JURY TRIAL

The Nation respectfully requests that all issues presented by its above Complaint be tried by a jury, with the exception of those issues that, by law, must be tried before the Court.

Date: July 9, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on July 9, 2018, I electronically filed the foregoing document using the Court's CM/ECF system, which will send notification to all counsel of record.

/s/ Joseph M. Callow, Jr.
Joseph M. Callow, Jr. (0061814)