IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

STATE OF DELAWARE, *ex rel.* MATTHEW P. DENN, Attorney General of the State of Delaware, **PLAINTIFF,** **v.** **PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN CORPORATION, ANDA PHARMACEUTICALS, INC., H. D. SMITH, LLC, CVS HEALTH CORPORATION, and WALGREENS BOOTS ALLIANCE, INC.,** **DEFENDANTS.**	C.A. No. _____ CCLD **TRIAL BY JURY OF 12 DEMANDED**

COMPLAINT

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Plaintiff, State of Delaware, *ex rel.* Matthew P. Denn, Attorney General of the State of Delaware, brings this 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., and Endo Pharmaceuticals Inc. (collectively, "Manufacturer Defendants"); (B) McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation, Anda Pharmaceuticals, Inc., and H. D. Smith, LLC, (collectively, "Distributor Defendants"); and (C) CVS Health Corporation and Walgreens Boots Alliance, Inc. (collectively, "Pharmacy Defendants").

INTRODUCTION

1. Prescription opioids are powerful pain-reducing medications. They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially-synthetic derivatives (such as hydrocodone and oxycodone), and fully-synthetic derivatives (such as fentanyl and methadone).

2. When used properly, prescription opioids can help manage pain for certain patients. Despite their potential uses, these drugs can cause addiction, overdose, and death, even when used properly. When used to treat chronic pain—or when used for non-medical purposes—those risks are amplified.

3. In recent years, the frequency of opioid use for both chronic pain and non-medical purposes has grown dramatically, resulting in an epidemic of prescription opioid abuse. According to the Centers for Disease Control and Prevention ("CDC"), Delaware lost 669 people to drug overdose deaths between 2014 and 2016, and the "main driver" of such deaths was prescription and illicit opioids.[1] Nationwide, millions of Americans are addicted to prescription opioids, and tens of thousands die annually from opioid overdoses.

4. Defendants' conduct resulted in this epidemic.

5. 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, Manufacturer Defendants nonetheless disseminated misstatements through multiple channels. This campaign includes websites, promotional materials, conferences, guidelines for doctors, and other vehicles.

6. Their aggressive marketing campaign enabled 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

[1] CDC, *Drug Overdose Death Data*, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last updated December 19, 2017) (189 deaths in 2014; 198 deaths in 2015; 282 deaths in 2016).

number of opioids prescribed nationwide. In fact, between 1999 and 2016, the number of opioids prescribed nationwide quadrupled.[2] Not surprisingly, deaths from prescription opioid use also quadrupled over the same period.[3]

7. 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 Delaware alone, data from the Substance Abuse and Mental Health Services Administration indicate that over 32,000 residents use prescription opioids for non-medical purposes.[5]

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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*, 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 (4.34% of people age 12 or older in Delaware engage in the non-medical use of prescription pain relievers).

8. This increase in non-medical demand and addiction has led to an increase in diversion. Diversion occurs whenever the supply chain of prescription opioids is broken and the 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 then transfer the pills to distribution companies—in particular Distributor Defendants, who together account for 85% of opioid shipments in the United States. Distributors (including Distributor Defendants) then supply opioids to pharmacies (including Pharmacy Defendants) and other healthcare providers, which then dispense the drugs to consumers.

10. At the distributor level, diversion occurs whenever opioid distributors fill suspicious orders from retailers such as pharmacies. As discussed below, under Delaware law, 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 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.

11. At the pharmacy level, diversion occurs whenever a pharmacist fills a prescription despite having reason to believe it was not being filled for a legitimate

medical purpose. A prescription may lack a legitimate medical purpose when a patient is either a drug dealer or opioid-dependent, seeks to fill multiple prescriptions from different doctors, 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 surrounding the transaction. Opioids are also diverted from retail outlets when they are stolen by employees or others, obtained through the use of stolen or forged prescriptions, or sold without prescriptions.

12. Of the 860,000 opioid prescriptions issued in Delaware each year (nearly one prescription per Delaware resident), studies suggest that as many as 110,000 of those prescriptions are diverted to non-medical uses.[6] These conclusions about the extent of opioid diversion are further supported by Drug

[6] The studies estimate that the percentage of prescription opioids that are diverted to illegitimate purposes ranges from 1.9 percent to 12.8 percent of total prescriptions. B.L. Wilsey et al., *Profiling Multiple Provider Prescribing of Opioids, Benzodiazepines, Stimulants, and Anorectics*, 112 Drug and Alcohol Dependence 99 (2010) (estimating that 12.8% of prescriptions are diverted); N. Katz et al., *Usefulness of Prescription Monitoring Programs for Surveillance–Analysis of Schedule II Opioid Prescription Data in Massachusetts*, *1996–2006*, 19 Pharmacoepidemioloy and Drug Safety 115 (2010) (estimating the diversion rate at 7.7% when defining likely diversion as patients that obtain opioids from at least 3 prescribers and at least 3 pharmacies in a year); D.C. McDonald & K.E. Carlson, *Estimating the Prevalence of Opioid Diversion by "Doctor Shoppers" in the United States*, 8 PLoS ONE (2013) (estimating the diversion rate at 1.9% of all prescriptions and 4% of total grams dispensed).

Enforcement Administration ("DEA") data showing that in the past few years Delaware has seen annual distribution exceeding 50 pills per resident and 440 pills per opioid user.[7]

13. As detailed below, Distributor Defendants and Pharmacy Defendants have legal obligations to combat diversion. Delaware laws and regulations require Distributor Defendants to refuse to fill suspicious orders and to conduct due diligence of customers submitting such orders. Delaware laws and regulations also require both Distributor Defendants and Pharmacy Defendants to maintain inventory security and control systems in order to prevent the diversion of controlled substances through loss, theft, or other means. Delaware laws and regulations also require pharmacists to exercise professional judgment in dispensing prescriptions, to address improper prescriptions, and to fill only prescriptions for a legitimate medical purpose. Distributor Defendants and Pharmacy Defendants have routinely and continuously violated these laws and

[7] 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.

regulations, 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 Distributor Defendants and Pharmacy 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 regarding diversion levied against multiple Distributor Defendants and Pharmacy Defendants.

14. The misconduct of Defendants, including their consistent failure to comply with their legal obligations, has led to an epidemic of prescription opioid abuse in Delaware. This epidemic resulted in 694 prescription opioid-related deaths in Delaware between 2007 and 2016, and 112 prescription opioid-related deaths in Delaware in 2016 alone,[8] and at least $100 million drained annually from

[8] CDC, Wide-ranging Online Data for Epidemiologic Research (WONDER), *Multiple Cause of Death Data, 1999–2016*, https://wonder.cdc.gov/mcd.html.

State resources for the healthcare,[9] criminal justice,[10] social services and welfare,[11] and education systems.[12]

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[9] Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis* 5 (2015), http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf (prescription opioid abuse costs the citizens and State of Delaware approximately $109 million in healthcare costs each year); Kohei Hasegawa et al., *Epidemiology of Emergency Department Visits for Opioid Overdose: A population-based study*, 89 Mayo Clinic Proceedings 462, 465, 467 (2014) (there are about two times as many opioid overdoses in Emergency Departments among publicly-insured individuals than among individuals with private insurance and publicly-insured individuals are approximately twice as likely to have a second visit to the Emergency Departments for opioid overdose as are privately-insured individuals); Cong. Research Serv., *Medicaid's Federal Medical Assistance Percentage (FMAP)* 14–15 (2016), https://fas.org/sgp/crs/misc/R43847.pdf (the State of Delaware pays for approximately 40% of publicly-funded healthcare expenses, or $29 million).

[10] The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets* 27 (2009), http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets (On average, state governments spend 12% more than their healthcare spending on the justice system expenses associated with substance abuse. Thus, compared to the $29 million Delaware spends on opioid-related healthcare, data suggest that the State spends almost $33 million annually on the costs of opioid abuse to the justice system.).

[11] The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets* 27 (2009), http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets (State governments spend 27% of the amount they spend on healthcare to fund the social services related to substance abuse. Applying this percentage to Delaware implies that the State spends almost $8 million annually on social services related to opioid abuse.).

[12] The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets* 27 (2009), http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets (State governments spend 77% of the amount they spend on healthcare on the K–12 education expenses associated

15. Damages suffered by the State (and State agencies) include the costs of (a) medical care, therapeutic and prescription drugs, and other treatments for patients suffering from opioid-related addiction, overdoses, or disease, or from medical conditions exacerbated by opioid abuse; (b) treatment of infants born with opioid-related addiction or medical conditions; (c) law enforcement and public safety measures necessitated by the opioid crisis; (d) opioid-related counseling and rehabilitation services; (e) welfare for children whose parents suffer from opioid-related disease or incapacitation; and (f) expenditures under Medicaid for purchases of prescription opioids for non-medical, illegitimate, or other improper purposes. Delaware has also suffered substantial damages relating to the lost productivity of Delaware citizens and Delaware businesses, and lower tax revenue for the State. Damages suffered by Delaware citizens include costs of unnecessary opioid prescriptions for chronic pain treatment, out-of-pocket expenditures on medical care, and other treatments related to opioids.

16. To remedy Defendants' misconduct, the State brings this action for (a) violations of Delaware's Consumer Fraud Act, (b) common law nuisance, (c) negligence, (d) unjust enrichment, and (e) civil conspiracy.

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with substance abuse. Using these data, Delaware is estimated to spend over $22 million annually to cover the burden of opioid abuse on the State's K–12 education system.).

17. The State seeks (a) a cease-and-desist order; (b) compensatory damages for the increased costs to Delaware's healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenue; (c) civil penalties under various provisions of the Delaware Code; (d) reimbursement of all payments fraudulently induced by Defendants' conduct; (e) disgorgement of all amounts unjustly obtained by Defendants; (f) restitution of all expenditures by the State and Delaware consumers resulting from Defendants' conduct; (g) punitive damages; (h) attorneys' fees and costs; and (i) such further relief as justice may require.

PARTIES

I. PLAINTIFF

18. Plaintiff, State of Delaware, *ex rel.* Matthew P. Denn, Attorney General of the State of Delaware, brings this action in the State's capacity as sovereign, in its proprietary capacity, and in a *parens patriae* capacity.

19. The Attorney General is statutorily authorized to initiate and maintain this action, and does so pursuant to 6 *Del. C.* § 2522 and 29 *Del. C.* § 2522. This action is also maintained pursuant to the Attorney General's common law *parens patriae* powers.

II. DEFENDANTS

A. Manufacturer Defendants

20. Defendant Purdue Pharma L.P. (together with Purdue Pharma Inc. and The Purdue Frederick Company, "Purdue") is a limited partnership organized and existing under the laws of the State of Delaware with its principal place of business located in Stamford, 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 in Delaware. Purdue Pharma L.P. has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

21. Defendant Purdue Pharma Inc. (together with Purdue Pharma L.P. and The Purdue Frederick Company, "Purdue") is a corporation organized and existing under the laws of New York State with its principal place of business located in Stamford, 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 in Delaware. Purdue Pharma Inc. has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

22. Defendant The Purdue Frederick Company (together with Purdue Pharma L.P. and Purdue Pharma Inc., "Purdue") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located in Stamford, Connecticut. During all relevant times, The Purdue Frederick Company has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold in Delaware. The Purdue Frederick Company has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

23. Defendant Endo Health Solutions Inc. (together with Endo Pharmaceuticals Inc., "Endo") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located in Malvern, Pennsylvania. During all relevant times, Endo Health Solutions Inc. has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold in Delaware. Endo Health Solutions Inc. has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

24. Defendant Endo Pharmaceuticals Inc. (together with Endo Health Solutions Inc., "Endo") is a corporation organized and existing under the laws of

the State of Delaware with its principal place of business located in Malvern, Pennsylvania. During all relevant times, Endo Pharmaceuticals Inc. has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold in Delaware. Endo Pharmaceuticals Inc. has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

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

B. Distributor Defendants

26. Defendant McKesson Corporation ("McKesson") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at One Post Street, San Francisco, CA 94104. McKesson is authorized to conduct business in Delaware. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in Delaware. McKesson has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

27. Defendant Cardinal Health, Inc. ("Cardinal") is a corporation organized and existing under the laws of the State of Ohio with its principal place of business located at 7000 Cardinal Place, Dublin, OH 43017. Cardinal is authorized to conduct business in Delaware. During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in Delaware. Cardinal has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

28. Defendant AmerisourceBergen Corporation ("AmerisourceBergen") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 1300 Morris Drive, Chesterbrook, PA 19087. AmerisourceBergen is authorized to conduct business in Delaware. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers in Delaware. AmerisourceBergen has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

29. Defendant Anda Pharmaceuticals, Inc. ("Anda") is a corporation organized and existing under the laws of the State of Florida with its principal place of business located at 2915 Weston Road, Weston, FL 33331. Anda is

authorized to conduct business in Delaware. During all relevant times, Anda has distributed substantial amounts of prescription opioids to providers and retailers in Delaware. Anda has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

30. Defendant H. D. Smith, LLC ("H. D. Smith") is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business located at 3606 Fiat Avenue, Springfield, IL 62703. H. D. Smith is authorized to conduct business in Delaware. During all relevant times, H. D. Smith has distributed substantial amounts of prescription opioids to providers and retailers in Delaware. H. D. Smith has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

31. As discussed further below, each of the Distributor Defendants has consistently failed to comply with its legal obligations concerning opioid diversion and many have paid civil penalties to resolve government allegations regarding opioid diversion.

C. Pharmacy Defendants

32. Defendant CVS Health Corporation ("CVS") is a corporation organized and existing under the laws of the State of Delaware with its principal

place of business located at One CVS Drive, Woonsocket, RI 02895. CVS is authorized to conduct business in Delaware. During all relevant times, CVS has sold and continues to sell prescription opioids at locations within Delaware, including in close proximity to Delaware's hospitals, clinics, and other healthcare facilities serving patients of Delaware's healthcare system. CVS has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

33. Defendant Walgreens Boots Alliance, Inc., f/k/a Walgreen Co. ("Walgreens") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 108 Wilmot Road, Deerfield, IL 60015. Walgreens is authorized to conduct business in Delaware. During all relevant times, Walgreens has sold and continues to sell prescription opioids at locations within Delaware, including in close proximity to Delaware's hospitals, clinics, and other healthcare facilities serving patients of Delaware's healthcare system. Walgreens has engaged in consensual commercial dealings with Delaware and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Delaware.

34. As discussed further below, each of the Pharmacy Defendants has consistently failed to comply with its legal obligations concerning opioid diversion,

and each has paid civil penalties to resolve government allegations regarding opioid diversion.

JURISDICTION AND VENUE

35. Jurisdiction of this Court is proper under Article IV, Section 7, of the Delaware Constitution and 10 *Del. C.* § 541.

36. This case qualifies for assignment to the Superior Court Complex Commercial Litigation Division because the amount in controversy exceeds One Million Dollars ($1,000,000).

37. This Court has personal jurisdiction over Defendants because each Defendant is, or was during the relevant time period, incorporated in Delaware or licensed to do business in Delaware; is transacting or has transacted business in Delaware; or has other significant contacts with Delaware. Each Defendant has sufficient contacts with Delaware to give rise to the current action, has continuous and systematic contacts with Delaware, or has consented either explicitly or implicitly to the jurisdiction of this Court.

FACTUAL BACKGROUND

I. PRESCRIPTION OPIOIDS ARE HIGHLY DANGEROUS

38. 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, government agencies have warned that opioids 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."[13]

39. Given these risks, the marketing, distribution, and sale of prescription opioids are heavily regulated under Delaware and Federal law. Delaware's Uniform Controlled Substances Act (16 *Del. C.* §§ 4701, *et seq.*), Uniform Controlled Substances Act Regulations (24 *Del. Admin. C.* CSA 1.0 *et seq.*) code sections regarding branding of drugs (*e.g.*, 16 *Del. C.* §§ 3302, *et seq.*), and numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances provide strict controls and requirements throughout the opioid distribution chain. These provisions of Delaware law also incorporate and reference Federal law regarding the marketing, distribution, and sale of prescription opioids, including the Federal Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, and the Federal Food, Drug, and Cosmetic Act, 21 U.S. §§ 321 *et seq.*

40. As discussed below, despite the dangers of prescription opioids, Manufacturer Defendants wrongfully marketed them through misleading

[13] Food and Drug Admin., *Opioid Medications*, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm (last updated July 14, 2017).

statements that minimized the risk of these drugs and failed to disclose accurately the true magnitude of those risks. The actions of Manufacturer Defendants created a huge market for prescription opioids, which in turn led to massive diversion of these drugs from legitimate to illegitimate channels. Distributor Defendants and Pharmacy Defendants, who have duties to prevent diversion, wrongfully turned a blind eye to it. As a result of the wrongful acts of the Defendants, Delaware and its citizens suffered injuries and damages.

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

41. Each Manufacturer Defendant has a legal obligation under Delaware statutory and common law to exercise reasonable care in the marketing, promotion, and sale of opioids.

42. Under Delaware law, "No person shall manufacturer, sell or trade in, within this State, any article of food or drugs which is . . . misbranded . . . within the meaning of this chapter." 16 *Del. C.* § 3302. The referenced chapter incorporates "the definition of misbranding in the Federal Food, Drug, and Cosmetic Act." *See* 16 *Del. C.* § 3308. The Federal Food, Drug, and Cosmetic Act defines misbranding to include misleading advertising. *See* 21 U.S.C. § 302(n). It further defines misleading advertising to include 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.

Id.

43. 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. MANUFACTURER DEFENDANTS VIOLATED THEIR DUTIES

A. 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

44. 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.

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

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

46. Manufacturer Defendants contributed content and funding to numerous "guidelines" on opioid use that misleadingly downplayed the risks of opioid addiction when prescribed for chronic pain. For instance, "A Policymaker's Guide to Understanding Pain & Its Management," an October 2011 American Pain Foundation pamphlet "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."[14] Similarly, "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain," a February 2009 article funded by the American Pain Society and written by several authors with financial ties to Manufacturer Defendants, promoted opioids as "safe and effective" for chronic pain treatment and indicated that the risk of addiction was manageable for all patients regardless of past drug abuse history.[15] Likewise, "Treatment Options: A Guide for People Living with Pain," a 2006 American Pain Foundation pamphlet

[14] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.
[15] 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.

financially supported by Purdue, instructed that addiction is rare and limited to certain extreme cases.[16] Endo also sponsored the American Pain Foundation; in 2010 alone, the organization received more than $2,500,000 from Endo.[17]

47. 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."[18] On information and belief, Endo distributed a pamphlet, "Living with Someone with Chronic Pain," which stated that most health care providers agree that most people do not develop an addiction.

48. Manufacturer Defendants ran websites that promoted similar misleading claims. For example, Endo sponsored two websites, painknowledge.com and painaction.com, which claimed as of 2004 and 2015, respectively, that "[p]eople who take opioids as prescribed usually do not become addicted" and "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

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[16] Am. Pain Found., *Treatment Options: A guide for people living with pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

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

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

49. 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."[19] 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."[20]

50. Manufacturer Defendants trained salesmen to minimize the risk of addiction when discussing opioids with doctors. For instance, Purdue salesmen were instructed to tell doctors that opioids' addiction risk was "less than one percent."[21]

51. Manufacturer Defendants sponsored training sessions where doctors were given similar misleading information regarding the risks of opioid addiction.

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[19] Endo Pharmaceuticals, *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004), https://perma.cc/QN86-62PK.
[20] *Id.*
[21] 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.

For example, Purdue sponsored training sessions in the late 1990s and early 2000s where opioid addiction was described as "exquisitely rare."[22]

52. All of these statements were contrary to scientific facts. The CDC has directly contradicted Manufacturer Defendants' representations that opioid addiction is rare when opioids are used properly. 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.[23] A 2016 CDC guideline discusses studies that found that as many as 26% of long-term users of opioids experience problems with addiction or dependence.[24]

53. Moreover, in August 2016, the U.S. Surgeon General published an open letter to physicians nationwide, worrying that "heavy marketing to doctors" had led many to be "taught – incorrectly – that opioids are not addictive when

[22] Barry Meier, *Pain Killer: A "wonder" drug's trail of addiction and death* 190 (2003).
[23] 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.
[24] *Id*.

prescribed for legitimate pain." This letter also noted the "devastating" results that followed from this misinformation.[25]

54. Findings by the Food and Drug Administration ("FDA") similarly belie 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.[26] And several published clinical studies finding double-digit rates of prescription drug abuse in chronic pain patients controvert Manufacturer Defendants' claims that addiction rates are only one percent.[27]

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[25] Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95-CUYC.

[26] Food and Drug Admin., Letter from Janet Woodcock, M.D., Dir. of 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-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

[27] 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

55. Similarly, a prominent neuropharmacologist at the Washington University School of Medicine in St. Louis, Missouri, 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.[28]

56. 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, the authors of the June 2017 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."[29]

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.

[28] Harriet Ryan, '*You Want a Description of Hell?*' *OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

[29] 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. Manufacturer Defendants Misleadingly Claimed that Patients Who Were Showing Signs of Addiction Were Not Actually Addicted

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

58. On information and belief, Purdue published a physician education pamphlet in 2011 that suggested that drug-seeking behavior could be a sign of such "pseudoaddiction," which the pamphlet described as "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." The pamphlet thus implied that seeking more opioids might actually be a sign of insufficiently treated pain. Purdue employed the term "pseudoaddiction" in numerous other marketing materials, including a 2007 book titled "Responsible Opioid Prescribing – A Physician's Guide."[30] On information and belief, Endo also published materials promoting "pseudoaddiction."

59. However, there is no scientific support for the concept of "pseudoaddiction," a term coined by Dr. J. David Haddox, the Vice President of

[30] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* (2007).

Health Policy for Purdue.[31] 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."[32]

60. The 2016 CDC Guideline rejects the concept of pseudoaddiction. Rather than recommending that opioid doses be increased if patients do not experience pain relief, the Guideline states that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer term use"[33] and that doctors should "reassess[] pain and function within 1 month" so as to "minimize risks of long-term opioid use . . . ."[34]

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

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

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[31] 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.
[32] 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.
[33] 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.
[34] *Id*. at 25.

62. Guidelines edited and sponsored by Purdue and Endo[35]—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 dose, 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."[36]

63. 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 at the College on the Problems of Drug Dependence, challenging the correlation between opioid dosage and overdose.[37] And in 2016, Purdue's Dr. Haddox falsely claimed that evidence does not show that Purdue's opioids are being abused in large numbers.

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[35] Am. Pain Found., *Annual Report* (2010), https://www.documentcloud.org/documents/277604-apf-2010-annual-report.
[36] 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.
[37] 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*

64. 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 their dosages.[38] 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."

65. Manufacturer Defendants made these statements despite strong contrary scientific evidence. The FDA has stated that the available data "suggest a relationship between increasing opioid dose and risk of certain adverse events."[39] The CDC has stated that there is "an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages," and has specifically recommended that doctors "avoid increasing doses" above 90 morphine milligram equivalents ("MME") per day. [40]

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relationship, CPDD 76th Annual Scientific Meeting Program (June 2014), http://cpdd.org/wp-content/uploads/2016/07/2014CPDDprogrambook.pdf.

[38] Endo Pharmaceuticals, *Understanding Your Pain: Taking oral opioid analgesics* (2004), https://perma.cc/QN86-62PK.

[39] Food and Drug Admin., Letter from Janet Woodcock, M.D., Dir. of 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-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

[40] Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and

66. Nonetheless, Manufacturer Defendants misrepresented the effects of escalating dosages to further their relentless pursuit of corporate profit. The ability to escalate dosages was critical to 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.

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

67. Manufacturer Defendants disseminated these misstatements to doctors through a wide array of sources, each designed to maximize impact and targeted to a specific receptive audience.

68. Manufacturer Defendants often delivered their misstatements through "opinion leaders"—doctors in the field of pain management who were heavily funded by Manufacturer Defendants. Manufacturer Defendants frequently used opinion leaders to deliver their message because they knew that doctors often place great confidence in seemingly independent peers.

Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

69. One notable opinion leader was Dr. Russell Portenoy, who held himself out as an unbiased expert on opioids but received substantial funding from Manufacturer Defendants. Dr. Portenoy gave, in his words, "innumerable" lectures and media appearances promoting opioids.[41] 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 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.[42] Dr. Portenoy later conceded that some of his statements were misleading. In December 2012, he was quoted as saying, "Did I teach about

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

[42] Russell Portenoy, *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.

pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[43]

70. Between 2001 and 2010, Purdue's "In the Face of Pain" website similarly presented the statements of opinion leaders who were portrayed as independent experts, including Dr. Portenoy and other doctors associated with the American Pain Foundation. The website not only failed to disclose that Purdue had paid many of these opinion leaders for other work, but also did not identify Purdue's involvement beyond a small copyright notice at the bottom of the website.[44]

71. Manufacturer Defendants also often disseminated their misstatements through industry groups that presented themselves to the public as independent patient advocacy organizations, but whose content and funding came largely from Manufacturer Defendants. These groups included the American Pain Foundation, the American Pain Society, and the American Academy of Pain Medicine. Much

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

[44] 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.

like the opinion leaders, these industry groups allowed Manufacturer Defendants to present their misstatements as if they came from unbiased experts.

72. These groups published many of the misleading "guidelines" described above, based on content and funding provided by Manufacturer Defendants, including: (1) "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain" (2009);[45] (2) "A Policymaker's Guide to Understanding Pain & Its Management" (2011);[46] and (3) "Treatment Options: A Guide for People Living with Pain" (2006).[47] In 2007, the American Pain Society repeated, at a Senate Judiciary Committee hearing, Manufacturer Defendants' misstatements that addiction was a "rare problem" for patients using opioids for chronic pain and that there was "no causal effect . . . between the marketing of [a particular opioid] and the abuse and diversion of the drug."[48]

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[45] 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.

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

[47] Am. Pain Found., *Treatment Options: A guide for people living with pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[48] *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.).

73. 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 Manufacturer Defendants because studies show that such events influence the attending practitioners' prescribing habits and views towards a drug.[49]

74. From 1996 to 2001, Purdue conducted more than 40 pain management and speaker training sessions at resorts to recruit and train physicians, nurses, and pharmacists as speakers on behalf of Purdue.[50] Purdue trained more than 5,000 people at these all-expenses-paid events.[51] In addition, the DEA has estimated that Purdue funded over 20,000 opioid pain-related educational programs between 1996 and July 2002 through direct sponsorship or financial grants.[52]

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[49] Ray Moynihan, *Doctors' Education: The invisible influence of drug company sponsorship*, 336 The BMJ 416 (Feb. 23, 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.

[50] U.S. Go'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.

[51] *Id*.

[52] *Id*.

75. Manufacturer Defendants also used direct salesmen to market opioids. These salesmen often received the majority of their compensation based on individual sales figures, ensuring that they were strongly motivated to present their audiences with misleading information minimizing the risks of opioids.[53]

76. Manufacturer Defendants not only issued misstatements through channels thought to be the most productive, but also targeted marketing to doctors who would be most receptive to the misstatements.

77. 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 this fact, stating that "[g]eneralists are adopting [opioid] therapy without adequate knowledge of pain management principles."[54] On information and belief, Manufacturer Defendants also directly targeted susceptible patients like veterans and the elderly.

78. Manufacturer Defendants developed methods to target specifically physicians who were already prescribing higher-than-average numbers of opioids.

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[53] *Id*.

[54] 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.

Purdue created a database to identify physicians with large numbers of chronic-pain patients (which also showed which physicians were simply the most frequent prescribers of opioids). This database has given Purdue extensive knowledge of where and how its drugs are being used across the country, including in Delaware, and has allowed Purdue to target doctors already susceptible to its message.[55]

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

79. The problems engendered by the deceptive and unfair marketing of opioids were specifically known by Manufacturer Defendants. Manufacturer Defendants were aware that 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 their misleading marketing.

80. In 2007, Purdue settled federal allegations that it had introduced misbranded drugs into interstate commerce. The settlement included over $700 million in payments to the United States and guilty pleas by three of Purdue's former executive officers.[56] Purdue acknowledged that "some employees made, or

[55] 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.
[56] Plea Agreement at 4, *United States of America v. The Purdue Frederick Co., Inc.*, Case No. 1:07-cr-00029-JPJ (W.D. Va. May 10, 2017).

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."[57]

81. On August 20, 2015, New York State concluded a multiyear investigation of Purdue and settled claims against the company related to its marketing and sales practices. Specifically, the agreement 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 provide information to health care providers about FDA-approved training programs regarding the appropriate prescription of opioids. The agreement also required Purdue to and cease marketing representations on its website "www.inthefaceofpain.com" implying that the website was neutral or unbiased, and to disclose the financial relationship Purdue's purported neutral experts have with the company.[58]

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[57] 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.

[58] 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

82. 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.[59]

83. In 2016, Endo settled claims with New York State and agreed to halt misleading advertisements it had been running there concerning the safety of opioids. New York 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."[60] 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 State found that Endo had no evidence for that statement.[61] Consistent with this finding, Endo agreed not to make statements in New York that opioids "generally

(August 20, 2015), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent.

[59] *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.

[60] 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.

[61] *Id.*

are non-addictive" or "that most patients who take opioids do not become addicted."[62]

84. 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."[63] In response to the misuse of opioids, Purdue said that "Corporations have a responsibility to address this issue, and Purdue has dedicated vast resources for helping to prevent drug abuse . . . ."[64]

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

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[62] *Id.*
[63] Purdue Pharma, *Combating Opioid Abuse*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/combating-opioid-abuse/ (last visited Nov. 07, 2017).
[64] *Id*.

prescription pain medications [that] can lead to tragic consequences, including addiction, overdose, and death."[65]

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."[66] Those policies employed by Purdue 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, among other things.

85. However, on information and belief, these representations are untrue. For example, notwithstanding its public statements of corporate responsibility, Purdue has failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the

[65] Purdue Pharma, *Responsible Use of Opioids*, http://www.purduepharma.com/patients-caregivers/responsible-use-of-opioids/ (last visited Nov. 07, 2017).
[66] Purdue Pharma, *Public Policies to Address the Opioid Crisis*, http://www.purduepharma.com/about/purdue-pharma-public-policy/ (last visited Nov. 07, 2017).

fight against opioid abuse" and "strong record of coordination with law enforcement."[67]

86. 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.[68] Endo made no such assertions before it faced financial competition regarding the drug.

87. Additionally, since at least 2002, Purdue has maintained a database of health care 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."[69]

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[67] *See* 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/; 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/.

[68] *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.

[69] *Id*.

88. 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.[70]

89. The Time's investigation also found that "for more than a decade, Purdue collected extensive evidence suggesting illegal trafficking of OxyContin" and yet consistently failed to report suspicious dispensing or to stop supplies to the pharmacy.[71] Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, 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 more than 1.1 million OxyContin tablets.[72]

D. Manufacturer Defendants' Conduct Violated Their Duties

90. 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 in Delaware, despite actual or constructive knowledge that the opioids were ultimately being consumed by Delaware citizens for unsafe and non-medical purposes.

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[70] *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/.
[71] *Id.*
[72] *Id.*

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

92. On information and belief, Manufacturer Defendants failed to take any of these steps to prevent their misrepresentations and omissions from contributing to the opioid epidemic.

IV. DISTRIBUTOR DEFENDANTS AND PHARMACY DEFENDANTS HAVE LEGAL DUTIES TO PREVENT OPIOID DIVERSION

93. Each Distributor Defendant and each Pharmacy Defendant has a common law duty to exercise reasonable care under the circumstances. In addition, each Distributor Defendant and each Pharmacy Defendant assumes a duty, when it speaks publicly about opioids, to speak accurately.

94. Moreover, Delaware and Federal laws and regulations impose duties on Distributor Defendants and Pharmacy Defendants, and create a standard of conduct to which Distributor Defendants and Pharmacy Defendants must adhere.

95. These statutes and regulations were designed to protect society from the harms of 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 Delaware's Uniform Controlled Substances Act (16 *Del. C.* §§ 4701, *et seq.*), Uniform Controlled Substances Act Regulations (24 *Del. Admin. C.* CSA 1.0 *et seq.*), and numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances, (collectively the "DE CSA"). The DE CSA provides strict controls and requirements throughout the opioid distribution chain. *See* 16 *Del. C.* §§ 4701 *et seq.* The Federal Controlled

Substances Act ("FCSA"), 21 U.S.C. §§ 801 *et seq.*, also strictly regulates the manufacture, distribution, and sale of these drugs.

96. Delaware 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, Distributor Defendants' and Pharmacy Defendants' violations of Delaware and Federal laws and regulations show that they failed to meet the relevant standard of care.

A. Delaware and Federal Law Set a Standard of Care for Distributor Defendants to Follow

97. On information and belief, each Distributor Defendant distributes opioids in the State of Delaware. In order to legally distribute drugs in the State of Delaware, a distributor must hold a valid wholesale distribution license for each facility from which it distributes drugs in the State.

98. Cardinal has no fewer than nine separate distribution facilities located throughout the country that hold Delaware licenses as wholesale drug distribution facilities. Cardinal has used some or all of those facilities to distribute opioids in the State of Delaware.

99. McKesson has no fewer than 18 separate distribution facilities located throughout the country that hold Delaware licenses as wholesale drug distribution facilities. On information and belief, McKesson has used some or all of those facilities to distribute opioids in the State of Delaware.

100. AmerisourceBergen has no fewer than seven separate distribution facilities located throughout the country that hold Delaware licenses as wholesale drug distribution facilities. On information and belief, AmerisourceBergen has used some or all of those facilities to distribute opioids in the State of Delaware.

101. Anda has no fewer than two separate distribution facilities located throughout the country that hold Delaware licenses as wholesale drug distribution facilities. On information and belief, Anda has used some or all of those facilities to distribute opioids in the State of Delaware.

102. H. D. Smith has no fewer than two separate distribution facilities located throughout the country that hold Delaware licenses as wholesale drug distribution facilities. H. D. Smith has used some or all of those facilities to distribute opioids in the State of Delaware.

1. Duties Under Delaware Laws and Regulations

103. The DE CSA requires distributors of controlled substances to take precautions to ensure a safe system for distribution of controlled substances, including opioids, and to prevent diversion of those controlled substances into illegitimate channels.

104. Delaware law requires any distributor that engages in activities related to controlled substances to register biennially with the Secretary of the Department of State. 16 *Del. C.* § 4732.

105. To obtain and maintain a permit to distribute opioids in the State, Distributor Defendants must, among other things, "establish, maintain, and adhere to written policies and procedures for: identifying, recording, and reporting losses or thefts" and have written policies and procedures for "reporting criminal or suspected criminal activities involving the inventory of a drug or drugs." 24 *Del. Admin. C.* § 2500-8.

2. Duties Under Federal Laws and Regulations

106. Like the DE CSA, the FCSA sets the standard of conduct to which Distributor Defendants must adhere. Also like the DE CSA, the FCSA requires all opioid distributors to maintain effective controls against opioid diversion and to employ a system to identify and report to law enforcement suspicious orders of controlled substances.

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

108. Importantly, Distributor Defendants must employ a system to inform the DEA of suspicious orders. *See* 21 C.F.R. § 1301.74(b).

109. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") accumulates data on 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. *See* 21 C.F.R. § 1304.33.

B. Delaware and Federal Law Set a Standard of Care for Pharmacy Defendants to Follow

110. The DE CSA and FCSA also impose specific obligations on Pharmacy Defendants. These requirements, along with their related regulations and agency interpretations, set a standard of care for pharmacy conduct.

111. CVS has 19 retail locations in the State of Delaware. CVS also has two wholesale distribution centers that are registered to ship into the State.

112. Walgreens has 65 retail locations in the State of Delaware.

1. Duties Under Delaware Laws and Regulations

113. The DE CSA imposes specific obligations on Pharmacy Defendants.

114. The DE CSA requires pharmacies to take precautions to ensure a safe system for distribution of controlled substances, including opioids, and to prevent diversion of those controlled substances into illegitimate channels. *See, e.g.*, 16 *Del. C.* § 4735(b)(1) ("The Secretary, after due notice and hearing may limit, suspend, fine or revoke the registration of any registrant who . . . (b) Has failed to

maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels . . .").

115. The State of Delaware also has sought to curb the diversion of opioids and other potentially dangerous drugs through the creation of the Delaware Prescription Monitoring Program ("PMP"). The PMP is a reporting system that monitors the flow of controlled substances, including opioids, within Delaware. It is an electronic program that aggregates the data submitted by dispensers of opioids and other controlled substances within Delaware.

116. The PMP shall be used, according to the statute, (a) to provide information to prescribers, dispensers, and patients to help avoid the illegal use of controlled substances; (b) to assist law enforcement to investigate illegal activity related to the prescribing, dispensing, and consumption of controlled substances; and (c) to minimize inconvenience to patients and prescribing practitioners while effectuating the collection and storage of prescription monitoring information. 16 *Del. C.* § 4798(c).

117. The PMP requires dispensers to submit certain information about each dispensation of opioids. *Id.* § 4798(d). The PMP can be aggregated and summarized, allowing the information to be used by law enforcement, the Office of Controlled Substances, or the Secretary of State to identify and prevent diversion.

118. Delaware regulations require that prescriptions for controlled substances must be issued for a legitimate medical purpose in the usual course of professional practice. The regulations provide that "[a]n order purporting to be a prescription not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of § 4738 of the Act and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violation of the provisions of law relating to controlled substances." 24 *Del. Admin. C.* § 42.1.

119. Moreover, a pharmacist is required to verify that the practitioner prescribing the controlled substance is registered to do so under Federal law and to verify the identity of the individual receiving the controlled substances through the presentation of one of a number of specified forms of identification. 24 *Del. Admin. C.* § 4.10.

120. Thus, under Delaware law, "[w]hen a [pharmacy] has a reasonable belief that a patient may be seeking a controlled substance [including opioids] for any reason other than the treatment of an existing medical condition, the dispenser shall obtain a patient utilization report regarding the patient for the preceding 12 months from the [PMP] before dispensing the prescription." 16 *Del. C.* § 4798(e).

121. Delaware professional regulations state that a pharmacist that knowingly engages in any activity which violates State and Federal laws and regulations governing the practice of pharmacy, like those described above, may merit discipline. 24 *Del. Admin. C.* § 2500-2.0.

122. Additionally, Delaware regulations require that pharmacists maintain a patient profile record system for all persons to whom prescriptions are dispensed. 24 *Del. Admin. C.* § 2500-5.1.10.

123. As set forth in these statutes and regulations, pharmacists are the last line of defense in keeping drugs from entering the illicit market. Pharmacists 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 one legally registered to dispense opioids, if the prescription is not for a legitimate medical purpose.

2. Duties Under Federal Laws and Regulations

124. 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.

125. 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.)

126. 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 who is approved and registered with the DEA to write prescriptions for opioids acting in the usual course of his professional practice.

127. 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."[73] 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 questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be [criminally] prosecuted."[74]

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[73] 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/.
[74] *Id*.

128. 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.

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

130. 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.

131. 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 order. 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 he or she has discovered a pattern of prescription abuse, the local Board of Pharmacy and the DEA must be contacted.

V. DISTRIBUTOR DEFENDANTS AND PHARMACY DEFENDANTS HAVE FAILED TO FULFILL THEIR DUTIES

A. Distributor Defendants Understood Their Duties and Violated Them Anyway

1. Distributor Defendants Understood and Acknowledged Their Duties

132. In addition to the Delaware and Federal law and regulations regarding controlled substances, Distributor Defendants received detailed, specific instructions for identifying and minimizing the risk of opioid diversion in their supply chains.

133. To combat the problem of opioid diversion, the DEA has provided readily-available guidance to distributors on the requirements of suspicious order reporting.

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

135. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes

that affect the drug supply chain and suspicious order reporting.[75] All of the major distributors attended at least one of these conferences.

136. On September 27, 2006, and again on December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the obligations of the distributor to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.[76]

137. The September 27, 2006, letter reminded distributors of their legal obligation to use due diligence to avoid filling orders that may be diverted into the illicit market. The letter explained that each distributor is required to exercise due care in confirming the legitimacy of all orders. It also described circumstances that could be indicative of diversion, including ordering (a) excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; (b) a disproportionate ratio of controlled substances to non-controlled prescription

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

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

drugs; (c) excessive quantities of a limited variety of controlled substances in combination with certain other drugs; and (d) the same controlled substance from multiple distributors.

138. The December 27, 2007, letter reminded distributors that suspicious orders must be reported when discovered and that monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised distributors that they must independently analyze a suspicious order before the 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 the distributor from legal responsibility.

139. Distributor Defendants were on notice that their own industry group, the Healthcare Distribution Management Association ("HDMA"), published Industry Compliance Guidelines, entitled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," that stressed the critical role of each member of the supply chain in distributing controlled substances.[77]

140. These industry guidelines further explained that, by being "[a]t the center of a sophisticated supply chain, distributors are uniquely situated to perform

[77] Healthcare Distrib. Mgmt. Ass'n (HDMA) *Industry Compliance Guidelines: Reporting suspicious orders and preventing diversion of controlled substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

due diligence in order to help support the security of controlled substances they deliver to their customers."[78]

141. Opioid distributors have themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they recognize their duty to curb the opioid epidemic.

142. One of Cardinal's executives 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."[79]

143. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[80]

144. At the very least, these assurances about constantly eliminating criminal activity from the supply chain and curbing the opioid epidemic created a

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[78] *Id*.
[79] Lenny Bernstein et al., *How Drugs Intended for Patients Ended up in the Hands of Illegal Users: 'No one was doing their job'*, The Washington Post (Oct. 22, 2016), http://wapo.st/2vCRGLt.
[80] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, The Washington Post (Dec. 22, 2016), http://wapo.st/2uR2FDy.

duty for Distributor Defendants to act reasonably by following through on their assurances.

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

145. 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 recovered by government agencies—including actions by the DEA related to violations of the FCSA.

a. Cardinal

146. Cardinal has paid a millions of dollars in multiple DEA and state actions relating to its improper management and distribution of opioids to pharmacies across the United States.

147. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States.[81] These allegations included failing to report to the DEA thousands of suspicious

[81] 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.

orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.

148. In 2012, Cardinal reached another settlement with the DEA relating to systemic opioid diversion in its Florida distribution center.[82] Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only 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.

149. In December 2016, Cardinal again settled charges that it had violated the FCSA, this time for $44 million.[83] The settlement covered DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida. The same Florida distribution center at the heart of the

[82] 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.

[83] 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.

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 Delaware and, on information and belief, distributes opioids in the State.

150. 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 prescription opioid abuse.[84]

b. McKesson

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

152. In May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that McKesson had failed to maintain effective controls

[84] 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.

against diversion of controlled substances.[85] McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine.

153. Following the 2008 settlement, McKesson was supposed to change its ways and fix its flawed processes to prevent 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 early 2017, it was reported that McKesson had agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.[86]

[85] 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.
[86] 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

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

155. 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.[87] Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.[88]

156. 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.[89] AmerisourceBergen was part of a drug

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[87] 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.

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

[89] 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.

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.

3. Despite Prior Regulatory Actions, Distributor Defendants Violated Their Duties in Delaware

157. Despite being penalized by law enforcement authorities, Distributor Defendants Cardinal, McKesson, and AmerisourceBergen 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.

158. 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 State of Delaware and its citizens.

159. In fact, Distributor Defendants have supplied and continue to supply quantities of prescription opioids in and around Delaware with the actual or constructive knowledge that the opioids were ultimately being consumed by Delaware 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.

160. Each Distributor Defendant knew, or should have known, that the amount of opioids that it allowed to flow into Delaware was far in excess of what

could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

161. 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 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 the 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 in and around Delaware; (e) informing pharmacies and retailers about opioid diversion; and (f) in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies.

162. On information and belief, Distributor Defendants made little to no effort to visit the pharmacies servicing Delaware to perform due diligence inspections to ensure that the controlled substances Distributor Defendants had furnished were not being diverted to illegal uses.

163. On information and belief, 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 Delaware, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

164. Under Title 24 of the Delaware Administrative Code Section 2500-8.0, wholesale distributors of prescription drugs are required to "[m]aintain records of sources of the drugs, the identity and quantity of the drugs received and distributed or disposed of, and the date of receipt and distribution or other disposition of the drugs." Distributors are further required to "[h]ave records available for inspection and photocopying by the authorized federal, state, or local law enforcement agency officials for a period of three (3) years following the disposition of the drugs. Records shall be kept at the inspection site or must be immediately retrievable by computer or other electronic means."

165. Each of the Distributor Defendants holds at least one Delaware license as a wholesale drug distributor pursuant to Title 24 of the Delaware Administrative Code.

166. In November 2017, pursuant to Title 24 of the Delaware Administrative Code, the State requested access to records of transactions in five specific opioid drugs from Distributor Defendants. Distributor Defendants

McKesson, AmerisourceBergen, and Anda have not produced records in response to those requests.

167. Cardinal did not make records immediately available in response to the State's request. Cardinal did make some records available more than seven weeks after they were required to have done so under Delaware law. Those records indicate that Cardinal had actual or constructive knowledge that the opioids it distributed in Delaware were ultimately being used for non-medical purposes.

168. H. D. Smith produced records in response to the State's request, and those records indicate that H. D. Smith had actual or constructive knowledge that the opioids it distributed in Delaware were ultimately being used for non-medical purposes.

B. Pharmacy Defendants Understood Their Duties and Violated Them Anyway

1. Pharmacy Defendants Understood and Acknowledged Their Duties

169. Pharmacy Defendants similarly had knowledge of not just the widespread public coverage of the prescription opioid epidemic, but also had industry-specific knowledge of the particular risks and harms from filling prescriptions for non-medical purposes and the resulting widespread opioid abuse.

170. The DEA,[90] state pharmacy boards,[91] and national industry associations[92] have provided extensive guidance to pharmacists concerning their duties to the public. The guidance teaches pharmacists how to identify red flags, which indicate to the pharmacist that there may be a problem with the legitimacy of a prescription presented by a patient.[93] The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

171. 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

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[90] 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/.

[91] Tex. State Bd. Of Pharmacy, *Abuse & Misuse of Prescription Drugs* (last visited Aug. 11, 2017), 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.

[92] 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.

[93] 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.

accomplice of the drug-seeker; (c) prescriptions written using fictitious patient names and addresses; and (d) other similar red flags.[94]

172. 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.

173. 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 State 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."[95]

174. 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."[96]

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[94] 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 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.

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

[96] 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-

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

175. 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 State, Pharmacy Defendants have breached their duties under the "reasonable care" standard of Delaware 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 Delaware and Federal laws and regulations.

176. Pharmacy Defendants were on notice of their ongoing negligence or reckless misconduct towards the State in part because of their history of being penalized for violating their duties and legal requirements in other jurisdictions.

a. CVS

177. 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 dispensing opioids in quantities significantly

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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.

higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the FCSA.

178. As recently as February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that its stores and pharmacists had been violating their duties under the FCSA and filling prescriptions with no legitimate medical purpose.[97] CVS has resolved similar allegations by settling with Florida ($22 million),[98] Oklahoma ($11 million),[99] Massachusetts and New Hampshire ($3.5 million),[100] Texas ($1.9 million),[101] and Rhode Island ($450,000).[102]

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[97] 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.

[98] 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.

[99] 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.

[100] 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.

[101] 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.

[102] 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,

179. 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.[103] 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 CVS stores. One of those stores filled 29 prescriptions for the forger over the course of just six months, totaling 1,290 pills, or seven pills per day, an inordinate amount under the circumstances. At a different store, the same individual was able to fill 28 prescriptions that she forged for herself and three other alleged patients, even though the prescriptions were identical in every respect other than the patient name. These prescriptions were presented just days apart. 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

2015), https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement.

[103] 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.

easily discovered by CVS pharmacists by checking the DEA website or calling the phone number on the prescriptions.

180. CVS also has settled allegations made by the DEA and DOJ that its stores and pharmacists had been violating their duty under the FCSA and filling prescriptions with no legitimate medical purpose.[104] 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 the FCSA and relevant regulations, including failing to comply with a pharmacist's responsibility to ensure that these prescriptions were issued for a legitimate medical purpose. CVS paid $8 million to settle these claims.

181. CVS also has settled allegations by the DOJ that some of its stores in Connecticut failed to maintain proper records in accordance with the FCSA.[105] On over 6,000 occasions, CVS stores in Connecticut failed to keep appropriate records of prescriptions and purchase invoices. CVS settled these allegations for $600,000.

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[104] 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.

[105] 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.

182. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the FCSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.[106] In order to fill otherwise illegitimate prescriptions, CVS pharmacists substituted valid DEA registration numbers of non-prescribing practitioners in its records. During that time period, the DEA also found numerous instances of CVS pharmacists substituting false DEA registration numbers in company computer systems, on paper prescriptions, and even in the information that the pharmacy reported to the State of Oklahoma's Prescription Drug Monitoring Program.[107]

b. Walgreens

183. 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 pain killers to be diverted for abuse and illegal black market sales.[108] As part of the

[106] 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.
[107] *See* Complaint, *U.S. v. CVS Pharmacies*, No. CIV-11-1124-HE (W.D. Okla. Oct. 5, 2011).
[108] 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

settlement, Walgreens agreed to enhance its training and compliance programs, and to cease compensating its pharmacists based on the volume of prescriptions filled. The settlement resolved investigations into and allegations of FCSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

184. 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 ten times the average amount.[109] They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 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 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

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Substances Act (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[109]Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the FCSA or the health of communities.[110]

185. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000)[111] and Massachusetts ($200,000).[112] 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), rather than seeking approval from the agency. In some cases, MassHealth had rejected the prescription; other times, MassHealth was never billed. In response, Walgreens simply agreed to update its policies and procedures

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[110] *Id*.

[111] 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.

[112] 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.

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

3. Despite Prior Regulatory Actions, Pharmacy Defendants Violated Their Duties in Delaware

186. Despite their extensive understanding of the risks and harms of opioid diversion set forth above, Pharmacy Defendants continue to fail to fulfill their obligations to prevent opioid diversion.

187. Pharmacy Defendants have engaged in a consistent, nationwide pattern and practice of illegally distributing opioids. That pattern and practice has also affected the State of Delaware and its citizens.

188. On information and belief, Pharmacy Defendants regularly filled prescriptions in circumstances where red flags were present.

189. On information and belief, Pharmacy Defendants regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably-prudent pharmacy.

190. On information and belief, 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.

191. On information and belief, Pharmacy Defendants utilize 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. 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 STATE AND ITS CITIZENS

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

A. Manufacturer Defendants' Misconduct Has Injured and Continues to Injure Delaware and Its Citizens

193. Manufacturer Defendants' marketing campaign has resulted in a significant increase in opioid usage: between 1999 and 2016 the number of opioids prescribed nationwide quadrupled.[113] Nationally, the number of people who take prescription opioids for non-medical purposes is now greater than the

[113] 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.

number of people who use cocaine, heroin, hallucinogens, and inhalants combined.[114]

194. Every year, millions of Americans misuse and abuse opioid pain relievers in ways that can lead to addiction, overdose, and death. Data from the CDC suggest that over 2.6 million Americans are opioid-dependent and over 16.5 million Americans use prescription opioids for non-medical purposes.

195. In Delaware alone, data from the Substance Abuse and Mental Health Services Administration indicate that over 32,000 residents use prescription opioids for non-medical purposes.[115] Similarly, DEA data shows that in the past few years, Delaware has seen annual distribution exceeding 50 pills per resident and 440 pills per opioid user,[116] which is far more than is medically necessary.

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

[115] 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 (4.34 percent of people age 12 or older in Delaware engage in the non-medical use of prescription pain relievers).

[116] 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.p

196. This growth in non-medical demand, addiction, and diversion has led to serious harm in Delaware and across the nation. The increase in opioid usage has led to levels of addiction that, according to the U.S. Surgeon General, have "devastated" communities across America.[117] 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.[118] In 2011, the CDC reported that overdose deaths from prescription opioids had reached "epidemic levels."[119] That year, 16,917 people died from a prescription opioid-related overdose, an increase of more than 20% over the previous three years.[120] Since then, the national death toll has continued to rise. In

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df; https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/report_yr_2016.pdf.

[117] Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95-CUYC.

[118] *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).

[119] 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.

[120] 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.

2014, 18,893 people died from a prescription opioid-related overdose.[121] In 2015, that number increased again to 22,598.[122] As discussed above, overdose deaths in the United States involving prescription opioids have quadrupled since 1999. In Delaware, CDC data shows that over 340 people died from prescription opioid overdoses from 2011–2015.[123]

197. It was reasonably foreseeable to Manufacturer Defendants that their deceptive and aggressive marketing of opioids in and around Delaware would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

198. It was reasonably foreseeable to Manufacturer Defendants that when at-risk users gained access to opioids based on deceptive and false marketing, tragic, preventable injuries would result, including abuse, addiction, overdoses, and death. It was also reasonably foreseeable that many of these injuries would be suffered by Delaware citizens, and that the costs of these injuries would be shouldered by the State.

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[121] 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.
[122] *Id.*
[123] CDC, Wide-ranging Online Data for Epidemiologic Research (WONDER), http://wonder.cdc.gov.

199. Manufacturer Defendants knew or should have known that their continuing efforts to employ deceptive and unfair marketing, despite being previously sanctioned by government agencies for such actions, would contribute to the opioid epidemic in Delaware, and would create access to opioids by at-risk and unauthorized users, which, in turn, would perpetuate the cycle of abuse, addiction, demand, and illegal transactions.

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

201. Manufacturer Defendants made substantial profits over the years based on the deceptive and unfair marketing of opioids in Delaware. Their participation and cooperation in a common enterprise has foreseeably caused injuries to the citizens of Delaware and financial damages to Delaware. Manufacturer Defendants knew that Delaware would be unjustly forced to bear the costs of these injuries and damages.

202. Manufacturer Defendants' deceptive and unfair marketing of prescription opioids to Delaware citizens showed a reckless disregard for the safety

of Delaware and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of Delaware and its citizens.

B. Distributor Defendants' Misconduct has Injured and Continues to Injure Delaware and Its Citizens

203. It was reasonably foreseeable to Distributor Defendants that their conduct in violating their duties under Delaware and Federal law and regulations and flooding the market in and around Delaware with highly-addictive opioids would allow opioids to be diverted into illegitimate channels for non-medical uses.

204. It was reasonably foreseeable to Distributor Defendants that, when unintended users gain access to opioids, tragic, preventable injuries will result, including addiction, overdoses, and death. It was also reasonably foreseeable that many of these injuries would be suffered by Delaware citizens, and that the costs of these injuries would be shouldered by the State.

205. Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to Delaware'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.

206. Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed in and around Delaware were being dispensed based on invalid or suspicious prescriptions. It was foreseeable that filling suspicious orders for opioids would cause harm to Delaware and its citizens.

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

208. The use of opioids by Delaware citizens who were addicted or who did not have a medically-necessary purpose for using opioids could not have occurred without the actions of Distributor Defendants. If Distributor Defendants had adhered to effective controls to guard against diversion that are required by Delaware and Federal law, the State and its citizens would have avoided significant injury.

209. Distributor Defendants made substantial profits based on the illegal diversion of opioids in Delaware. Distributor Defendants' participation and cooperation in a common enterprise has foreseeably caused injuries to Delaware's citizens and financial damages to the State. Distributor Defendants knew full well that Delaware would be unjustly forced to bear the costs of these injuries and damages.

210. Distributor Defendants' distribution of excessive amounts of prescription opioids to Delaware showed a reckless disregard for the safety of the

State and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of the State.

211. At all relevant times, Distributor Defendants engaged in these activities, and continue to do so, knowing that the State, 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.

212. It was reasonably foreseeable to Distributor Defendants that the State would be forced to bear substantial expenses as a result of Distributor Defendants' acts.

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

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

214. It was reasonably foreseeable to Pharmacy Defendants that filling invalid or suspicious prescriptions for opioids would cause harm to Delaware and its citizens.

215. It was reasonably foreseeable to Pharmacy Defendants that, when unintended users gained access to opioids, tragic preventable injuries would result,

including overdoses and death. It was also reasonably foreseeable many of these injuries would be suffered by Delaware and its citizens.

216. Pharmacy Defendants were aware of widespread prescription opioid abuse in and around Delaware, but they nevertheless persisted in filling invalid or suspicious prescriptions for opioids and failed to take steps to address this misconduct.

217. The use of opioids by Delaware 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 adhered to effective controls to guard against diversion, Delaware and its citizens would have avoided significant injury.

218. Pharmacy Defendants made substantial profits from the diversion of opioids in Delaware. Their participation and cooperation in a common enterprise has foreseeably caused injuries to Delaware's citizens and financial damages to the State. Pharmacy Defendants knew that Delaware would be unjustly forced to bear the costs of these injuries and damages.

219. 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.

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

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

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

D. Defendants' Misconduct Has Damaged Delaware and Its Citizens

223. Defendants' misleading marketing and failure to prevent opioid diversion in and around Delaware 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 Delaware's resources and those of its counties and municipalities are devoted to addiction-related problems. Meanwhile, the prescription opioid crisis

diminishes Delaware's available workforce, decreases productivity, increases poverty, and consequently requires greater State and local expenditures.

224. These costs to the State are estimated to include $29 million in additional costs to Delaware's healthcare system,[124] $33 million in additional costs to Delaware's justice system,[125] $8 million in additional costs to Delaware's social

[124] Matric Global Advisors, *Health Care Costs from Opioid Abuse: A state-by-state analysis*, 5 (2015), http://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf (prescription opioid abuse costs the citizens and State of Delaware approximately $109 million in healthcare costs each year); Kohei Hasegawa et al., *Epidemiology of Emergency Department Visits for Opioid Overdose: A population-based study*, 89 Mayo Clinic Proceedings 462, 465, 467 (2014) (there are about two times as many opioid overdoses in Emergency Departments among publicly-insured individuals than among individuals with private insurance and publicly-insured individuals are approximately twice as likely to have a second visit to the Emergency Departments for opioid overdose as are privately-insured individuals); Congressional Research Serv., *Medicaid's Federal Medical Assistance Percentage (FMAP)* 14–15 (2016), https://fas.org/sgp/crs/misc/R43847.pdf (the State of Delaware pays for approximately 40% of publicly-funded healthcare expenses, or $29 million).

[125] The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets*, 27 (May 2009), http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets (On average, state governments spend 12% more than their healthcare spending on the justice system expenses associated with substance abuse. Thus, compared to the $29 million Delaware spends on opioid-related healthcare, data suggests that the State spends almost $33 million annually on the costs of opioid abuse to the justice system.).

services,[126] and $22 million in additional costs to Delaware's education system,[127] as well as at least $29 million in lost productivity and substantially lower tax revenue.[128]

COUNT I
CONSUMER FRAUD
(Against Manufacturer Defendants)

225. Delaware realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

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[126] The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets*, 27 (May 2009), http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets (State governments spend 27% of the amount they spend on healthcare to fund the social services related to substance abuse. Applying this percentage to Delaware implies that the State spends almost $8 million annually on social services related to opioid abuse.).

[127] The Nat'l Ctr. on Addiction and Substance Abuse, *Shoveling Up II: The impact of substance abuse on federal, state, and local budgets*, 27 (May 2009), http://www.centeronaddiction.org/addiction-research/reports/shoveling-ii-impact-substance-abuse-federal-state-and-local-budgets (State governments spend 77% of the amount they spend on healthcare on the K–12 education expenses associated with substance abuse. Using these data, Delaware is estimated to spend over $22 million annually to cover the burden of opioid abuse on the State's K–12 education system.).

[128] Howard Birnbaum et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 Pain Med. 657, 661 (2011); Scott Strassels, *Economic Burden of Prescription Opioid Misuse and Abuse*, 15 J. of Managed Care & Specialty Pharmacy 556 (2009); Ryan Hansen et al., *Economic Costs of Nonmedical Use of Prescription Opioids*, 27 The Clinical J. of Pain 194 (2011) (All studies estimate that the lost productivity costs are *at least* as large as the healthcare costs resulting from opioid abuse, and possibly as large as ten times annual healthcare costs.).

226. In marketing and selling prescription opioids, Manufacturer Defendants have persistently (i) misrepresented material facts, or (ii) suppressed, concealed, or omitted material facts, with the intent that consumers will rely thereon. Manufacturer Defendants:

a. have ignored Delaware laws that prohibit misbranding drugs;

b. have marketed drugs through misstatements and omissions of facts regarding the safety of those drugs; and

c. have failed adequately to guard against misstatements and omissions concerning opioids.

227. Manufacturer Defendants have misrepresented material facts, or used concealment, suppression, or omission of material facts with the intent that others rely upon such concealment, suppression, or omission, in connection with the manufacture and sale of prescription opioids, whether or not any person has been misled, deceived, or damaged thereby, in violation of § 2513(a) of the Delaware Consumer Fraud Act, by misrepresenting, suppressing, concealing, or omitting the material facts set forth in the preceding paragraph.

228. Each instance where the Defendants have manufactured or sold prescription opioids and misrepresented material facts or suppressed, concealed, or omitted any of the material facts set forth herein with the intent that a consumer

would rely thereon, constitutes a violation of § 2513(a) of the Delaware Consumer Fraud Act.

COUNT II
NUISANCE
(Against Manufacturer Defendants)

229. Delaware realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

230. The Attorney General is authorized to bring suit on behalf of the State and its citizens to address a public nuisance.

231. 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 State by unlawfully marketing prescription opioids through misleading statements in ways that facilitate the sale, distribution, and dispensing of such drugs from premises in and around Delaware to unauthorized users in Delaware—including children, people at risk of overdose or suicide, and criminals.

232. 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 in and around Delaware;

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.

233. 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 Delaware;

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

c. is proscribed by Delaware and Federal statutes;

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

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

234. The nuisance has undermined, is undermining, and will continue to undermine Delaware citizens' public health, quality of life, and safety. It has resulted in increased crime and property damage within Delaware. It has resulted in high rates of addiction, overdoses, and dysfunction within Delaware families and entire communities.

235. Public resources have been, are being, and will be consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources which could be used to benefit the Delaware public at large.

236. Manufacturer Defendants' nuisance-causing activities have not been, are not being, and will not be outweighed by the utility of the Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately-recognized societal interest in marketing opioids through misleading statements.

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

238. As a direct and proximate result of the nuisance, Delaware and its counties and municipalities have sustained economic harm by spending substantial sums trying to fix the societal harms caused by Manufacturer Defendants' nuisance-causing activity, including costs to the healthcare, criminal justice, social services, welfare, and education systems.

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

COUNT III
NEGLIGENCE
(Against Manufacturer Defendants)

240. Delaware realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

241. Manufacturer Defendants owe a duty to Delaware to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

242. The conduct of 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 in and around Delaware 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 Delaware by marketing opioids in violation of Delaware and Federal laws;

d. failing to adhere to all applicable law 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.

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

244. Each Manufacturer Defendant marketed opioids using misleading statements and omissions knowing that (a) there was a substantial likelihood this marketing would lead to sales illicit and non-medical purposes; and (b) opioids are an inherently dangerous product when used for chronic pain and non-medical purposes.

245. 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.

246. Each Manufacturer Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in marketing and introducing into commerce dangerous controlled substances.

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

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

249. Delaware is without fault, and its injuries would not have happened in the ordinary course of events if Manufacturer Defendants had used due care commensurate to the dangers involved in the marketing of controlled substances.

250. The reckless, wanton, and reprehensible nature of Manufacturer Defendants' conduct entitles Delaware to an award of punitive damages and attorneys' fees and costs.

COUNT IV
UNJUST ENRICHMENT
(Against Manufacturer Defendants)

251. Delaware realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

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

253. The estimated expenditures of $29 million annually by Delaware in providing healthcare services to people who use opioids have added to Manufacturer Defendants' wealth. The expenditures by Delaware have helped sustain Manufacturer Defendants' businesses.

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

255. Delaware has also expended substantial amounts of money paying for purchases by unauthorized users of prescription opioids illegally marketed by Manufacturer Defendants.

256. In this way, the State has conferred a benefit upon Manufacturer Defendants.

257. Manufacturer Defendants made substantial profits while fueling the prescription opioid epidemic in Delaware.

258. Manufacturer Defendants continue to receive considerable profits from the sale of controlled substances in Delaware.

259. Manufacturer Defendants are aware of these obvious benefits, and retention of these benefits is unjust.

260. Manufacturer Defendants have been unjustly enriched by these benefits.

261. It would be inequitable to allow Manufacturer Defendants to retain these benefits.

COUNT V
CONSUMER FRAUD
(Against Distributor Defendants and Pharmacy Defendants)

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

263. In distributing and dispensing prescription opioids, Distributor Defendants and Pharmacy Defendants have persistently (i) misrepresented material facts, or (ii) suppressed, concealed, or omitted material facts with the intent that consumers will rely thereon. Distributor Defendants and Pharmacy Defendants have misrepresented or concealed the material facts that they:

a. have failed to report suspicious orders of controlled substances;

b. have failed to maintain necessary records of opioid transactions;

c. have deliberately ignored questionable and obviously illegal prescriptions and filled them anyway;

d. have failed to implement effective business practices to guard against diversion of highly-addictive opioid products;

e. have turned a blind eye to the sale of prescription opioids to the citizens of Delaware in quantities that far exceeded the number of prescriptions that could reasonably have been used for medical purposes, despite information provided by prescribing records, pharmacy orders, and field reports from sales representatives; and

f. have violated the Delaware and Federal laws and regulations by (i) habitually filling suspicious or invalid orders for prescription opioids at the wholesale and retail levels; (ii) failing to maintain effective controls against opioid diversion; and (iii) failing to operate a system to disclose suspicious orders of controlled substances.

264. Distributor Defendants and Pharmacy Defendants have (a) misrepresented material facts, or (b) used concealment, suppression, or omission of material facts with the intent that others rely upon such concealment, suppression, or omission, in connection with the sale, distribution, or dispensing of prescription opioids, whether or not any person has been misled, deceived or

damaged thereby, in violation of § 2513(a) of the Delaware Consumer Fraud Act, by suppressing, concealing, or omitting the material facts set forth in the preceding paragraph.

265. Each instance where Distributor Defendants and Pharmacy Defendants have sold, distributed, or dispensed prescription opioids and suppressed, concealed or omitted any of the material facts set forth herein with the intent that a consumer would rely thereon, constitutes a violation of § 2513(a) of the Delaware Consumer Fraud Act.

COUNT VI
NUISANCE
(Against Distributor Defendants and Pharmacy Defendants)

266. Delaware realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

267. The Attorney General is authorized to bring suit on behalf of the State and its citizens to address a public nuisance.

268. Distributor Defendants and Pharmacy 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 State by unlawfully:

a. facilitating the diversion of prescription opioids by selling, distributing, or dispensing, or facilitating the sale, distribution, or dispensing of,

such drugs from premises in and around Delaware to unauthorized users in Delaware—including children, people at risk of overdose or suicide, and criminals;

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

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

d. using property for repeated unlawful sales of controlled substances.

269. 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 in and around Delaware;

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.

270. Distributor Defendants and Pharmacy 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 Delaware;

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

c. is proscribed by Delaware and Federal statutes and regulations, including the DE CSA and FCSA;

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

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

271. The nuisance has undermined, is undermining, and will continue to undermine Delaware citizens' public health, quality of life, and safety. It has resulted in increased crime and property damage within Delaware. It has resulted in high rates of addiction, overdoses, and dysfunction within Delaware families and entire communities.

272. Public resources have been, are, and will continue to be consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources which could be used to benefit the Delaware public at large.

273. Distributor Defendants' and Pharmacy Defendants' nuisance-causing activities have not been, are not being, and will not be outweighed by the utility of 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.

274. At all times, Distributor Defendants and Pharmacy Defendants possessed the responsibility, right and ability to control the sale, distribution, or dispensing of prescription opioids in Delaware. Distributor Defendants had the power to shut off the supply of illicit opioids into Delaware, and Pharmacy Defendants had the power to prevent the sale of opioids in Delaware for non-medical purposes.

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

276. As a direct and proximate result of the nuisance, Delaware and its counties and municipalities have sustained economic harm by spending substantial sums trying to fix the societal harms caused by Defendants' nuisance-causing activity, including costs to the healthcare, criminal justice, social services, welfare, and education systems.

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

COUNT VII
NEGLIGENCE
(Against Distributor Defendants and Pharmacy Defendants)

278. Delaware realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

279. Distributor Defendants and Pharmacy Defendants owe a duty to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

280. The conduct of Distributor Defendants and Pharmacy Defendants fell below the reasonable standard of care. Their negligent acts include the following:

a. oversupplying the market in and around Delaware 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 Delaware by disregarding precautionary measures built into the DE CSA and FCSA;

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.

281. Each Distributor Defendant and Pharmacy Defendant had a responsibility to control the sale, distribution, or dispensing of prescription opioids.

282. Each Distributor Defendant and Pharmacy Defendant sold prescription opioids in the supply chain 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 an inherently dangerous product when used for non-medical purposes.

283. Distributor Defendants and Pharmacy 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.

284. Distributor Defendants and Pharmacy Defendants were also negligent or reckless in failing to guard against foreseeable third-party negligence or misconduct, such as the foreseeable conduct of negligent or corrupt prescribers, corrupt pharmacists and staff, and criminals who buy and sell opioids for non-medical purposes.

285. Each Distributor Defendant and Pharmacy Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

286. Distributor Defendants and Pharmacy Defendants are in a limited class of registrants authorized to distribute and sell controlled substances in Delaware. This places Distributor Defendants and Pharmacy Defendants in a position of great trust and responsibility to Delaware. Distributor Defendants and

Pharmacy Defendants owe a special duty to Delaware; the duty owed cannot be delegated to another party.

287. Distributor Defendants and Pharmacy Defendants were also negligent or reckless in voluntarily undertaking duties to the State that they breached. Distributor Defendants and Pharmacy 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.

288. Distributor Defendants and Pharmacy Defendants' conduct was the cause-in-fact and proximate cause of injuries and damages to Delaware, its counties, municipalities and its citizens, including but not limited to the following: increased costs for healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenues.

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

290. The reckless, wanton, and reprehensible nature of Distributor Defendants and Pharmacy Defendants' conduct entitles Delaware to an award of punitive damages and attorneys' fees and costs.

COUNT VIII
UNJUST ENRICHMENT
(Against Distributor Defendants and Pharmacy Defendants)

291. Delaware realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

292. Delaware has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Distributor Defendants' and Pharmacy Defendants' conduct.

293. Delaware's expenditures in providing healthcare services to people who use opioids have added to Distributor Defendants' and Pharmacy Defendants' wealth. The expenditures by Delaware have helped sustain Distributor Defendants' and Pharmacy Defendants' businesses.

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

295. Delaware has also expended substantial amounts of money paying for purchases by unauthorized users of prescription opioids from Distributor Defendants' and Pharmacy Defendants' supply chain for non-medical purposes.

296. In this way, Delaware has conferred a benefit upon Distributor Defendants and Pharmacy Defendants.

297. Distributor Defendants and Pharmacy Defendants made substantial profits while fueling the prescription opioid epidemic in Delaware.

298. Distributor Defendants and Pharmacy Defendants continue to receive considerable profits from the sale, distribution, and dispensing of controlled substances in Delaware.

299. Distributor Defendants and Pharmacy Defendants are aware of these obvious benefits, and that retention of these benefits is not justified under these circumstances.

300. Distributor Defendants and Pharmacy Defendants have been unjustly enriched by these benefits.

301. It would be inequitable to allow Distributor Defendants and Pharmacy Defendants to retain these benefits.

COUNT IX
CIVIL CONSPIRACY
(Against Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants)

302. Delaware realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

303. 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 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.

304. In response to and in conjunction with this increased demand, Distributor Defendants continuously supplied prescription opioids to Pharmacy Defendants, which then dispensed these prescription opioids. These transactions occurred despite Distributor Defendants and Pharmacy Defendants having actual or constructive knowledge that they were habitually breaching their common law duties and violating the DE CSA and FCSA.

305. Without Manufacturer Defendants' misrepresentations, which created demand, Distributor Defendants would not have been able to sell to Pharmacy Defendants the increasing number of orders of prescription opioids for non-medical purposes throughout Delaware.

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

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

308. As a result of the concerted action between Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants, Delaware law was continually violated by the provision of opioids throughout the supply chain.

309. As a result of the concerted action between Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants, Delaware and its citizens have suffered damages.

310. Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants need not have expressly agreed to this course of action; concerted conduct itself is sufficient.

311. Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants are jointly and severally liable for the results of their concerted efforts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Delaware, prays that this Court enter judgment in its favor against Defendants and:

a. On Count I (Consumer Fraud Against Manufacturer Defendants),

i. Enter an order that directs Manufacturer Defendants to "cease and desist the[ir] unlawful conduct prospectively," i.e., cease and desist violating

the Delaware Consumer Fraud Act, 6 *Del. C.* §§ 2511, *et seq.*, in connection with the marketing, manufacture, and sale of prescription opioids;

ii. Enter an order levying penalties against Manufacturer Defendants, jointly and severally, in the amount of $10,000 per violation for each and every instance where they breached the provisions of the Delaware Consumer Fraud Act;

iii. Award Delaware such additional relief as may be necessary to remedy Manufacturer Defendants' violations of the Delaware Consumer Fraud Act, including the "return [of] any moneys obtained unlawfully," "order[s of] restitution, rescission, recoupment, or [any] other relief appropriate to prevent [Manufacturer Defendants] from being unjustly enriched"; and

iv. Award Delaware 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 (Nuisance Against Manufacturer Defendants),

i. Order Manufacturer Defendants to pay the expenses Delaware, its counties and municipalities have incurred or will incur in the future to abate fully the nuisance they have caused;

ii. Award Delaware punitive damages; and

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

c. On Count III (Negligence Against Manufacturer Defendants),

i. Award Delaware compensatory damages for the increased costs to Delaware's healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenue due to Manufacturer Defendants' negligence;

ii. Award Delaware punitive damages;

iii. Award Delaware attorneys' fees and costs; and

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

d. On Count IV (Unjust Enrichment Against Manufacturer Defendants),

i. Award Delaware restitution of its costs caused by Manufacturer Defendants' actions, including the costs of addressing Defendants' externalities and the costs of prescription opioids paid for by the State;

ii. Disgorge Manufacturer Defendants of all amounts they have unjustly obtained; and

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

e. On Count V (Consumer Fraud Against Distributor Defendants and Pharmacy Defendants),

i. Enter an order that directs Distributor Defendants and Pharmacy Defendants to "cease and desist the[ir] unlawful conduct prospectively," i.e., cease and desist violating the Delaware Consumer Fraud Act, 6 *Del. C.*

§§ 2511, *et seq.*, in connection with the sale, distribution, or dispensing of prescription opioids;

ii. Enter an order levying penalties against Distributor Defendants and Pharmacy Defendants, jointly and severally with each other, in the amount of $10,000 per violation for each and every instance where they breached the provisions of the Delaware Consumer Fraud Act;

iii. Award Delaware such additional relief as may be necessary to remedy Distributor Defendants' and Pharmacy Defendants' violations of the Delaware Consumer Fraud Act, including the "return [of] any moneys obtained unlawfully," "order[s of] restitution, rescission, recoupment, or [any] other relief appropriate to prevent [Distributor Defendants and Pharmacy Defendants] from being unjustly enriched"; and

iv. Award Delaware 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.

f. On Count VI (Nuisance Against Distributor Defendants and Pharmacy Defendants),

i. Order Distributor Defendants and Pharmacy Defendants to pay the expenses Delaware, its counties and municipalities have incurred or will incur in the future to abate fully the nuisance they have caused;

ii. Award Delaware punitive damages; and

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

g. On Count VII (Negligence Against Distributor Defendants and Pharmacy Defendants),

i. Award Delaware compensatory damages for the increased costs to Delaware's healthcare, criminal justice system, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenue due to Distributor Defendants' and Pharmacy Defendants' negligence;

ii. Award Delaware punitive damages;

iii. Award Delaware attorneys' fees and costs; and

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

h. On Count VIII (Unjust Enrichment Against Distributor Defendants and Pharmacy Defendants),

i. Award Delaware restitution of its costs caused by Distributor Defendants' and Pharmacy Defendants' actions, including the costs of addressing Distributor Defendants' and Pharmacy Defendants' externalities and the costs of prescription opioids paid for by the State;

ii. Disgorge Distributor Defendants and Pharmacy Defendants of all amounts they have unjustly obtained; and

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

i. On Count IX (Civil Conspiracy Against Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants),

i. Award Delaware compensatory and punitive damages for the conspiracy in which Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants engaged; and

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

REQUEST FOR JURY TRIAL

Delaware 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: January 19, 2018

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