FOR IMMEDIATE RELEASE: **Contact:** James Hallinan

December 20, 2017 (505) 660-2216

Attorney General Balderas Adds New Defendants & Claims to Opioid Lawsuit

Albuquerque, NM – Today, **New Mexico Attorney General Hector Balderas** announced the addition of new claims and three new defendants to his lawsuit against companies he alleges are responsible for the opioid epidemic in New Mexico. Following additional investigation, **Balderas** made the decision to amend New Mexico's original complaint both to allege an industry-wide effort among manufacturers and distributors to unlawfully increase opioid sales in New Mexico, and to name additional defendants for their part in creating the epidemic.

"The entire pharmaceutical opioid industry, including both manufacturers and distributors together, has been in on the scheme to illegally market and sell opioids to New Mexicans, and we've modified our complaint to show that," said **Attorney General Balderas**.

Through his office's Consumer and Environmental Protection Division, **Balderas** filed his original complaint on September 7th of this year. A month later, *60 Minutes* and *The Washington Post* jointly published a story detailing the drug industry's efforts to undermine federal regulations aimed at stemming the flow of opioids into towns and cities across the country. According to the stories, dozens of drug companies, including those named in New Mexico's complaint filed today, spent more than $100 million lobbying for a bill virtually eliminating the federal Drug Enforcement Agency's ability to freeze suspicious shipments of opioids despite an ever-increasing number of opioid-related deaths.

"These stories really highlight the kinds of industry-wide deceit and fraud we've been uncovering through our own investigation, and they confirm for me that we are absolutely on the right track," said **Attorney General Balderas**. "These companies are willing to do whatever it takes to keep the profits rolling in. We cannot allow that behavior to continue."

Please see attached for a copy of the amended complaint.

Background:

60 Minutes Story: https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/

The Washington Post Story: https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.552e9cb076eb

# # #

FIRST JUDICIAL DISTRICT COURT
COUNTY OF SANTA FE
STATE OF NEW MEXICO

STATE OF NEW MEXICO, EX REL., HECTOR BALDERAS, ATTORNEY GENERAL,	§	
	§	NO. D-101-CV-2017-02541
Plaintiff,	§	
	§	
vs.	§	
	§	
PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; INSYS THERAPEUTICS, INC.; McKESSON CORPORATION; CARDINAL HEALTH INC.; CARDINAL HEALTH 105, LLC; CARDINAL HEALTH 108, LLC; CARDINAL HEALTH 110, LLC;	§	

CARDINAL HEALTH 200, LLC;	§
CARDINAL HEALTH 414, LLC;	§
CARDINAL HEALTH PHARMACY	§
SERVICES, LLC; and	§
AMERISOURCEBERGEN DRUG	§
CORPORATION,	§
	§
Defendants.	§

PLAINTIFF'S FIRST AMENDED COMPLAINT FOR DAMAGES, RESTITUTION, AND CIVIL PENALTIES

Plaintiff, the State of New Mexico, by Hector Balderas, Attorney General (the "State"), brings this First Amended Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan plc f/k/a Actavis plc; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; Insys Therapeutics, Inc.; McKesson Corporation; Cardinal Health, Inc.; Cardinal Health 105, LLC; Cardinal Health 108, LLC; Cardinal Health 110, LLC; Cardinal Health 200, LLC; Cardinal Health 414, LLC; Cardinal Health Pharmacy Services, LLC; and AmerisourceBergen Drug Corporation (collectively "Defendants") and alleges, upon information and belief, as follows:

I. INTRODUCTION

1. The State of New Mexico brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance in this State, and to recoup

State monies that have been spent as a result of Defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids (hereinafter "opioids").

2. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[1]

3. The Centers for Disease Control recently estimated that prescription opioid misuse costs the United States $78.5 billion per year, taking into account healthcare expenses, lost productivity, addiction treatment, and criminal justice involvement.[2] In 2015, over 33,000 Americans died as a result of opioid overdose, while an estimated 2 million people in the United States suffered from substance abuse disorders relating to prescription opioids.[3]

4. Since 2008, New Mexico has had one of the highest rates of drug overdose death in the United States. Between 2008 and 2012, almost every county in New Mexico had a higher drug overdose death rate than the rate for the entire United States. In Rio Arriba County and Mora County, overdose death rates were more than **five times** the national rate:[4]

---

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

[2] See Curtis S. Florence, et al., The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, 54 Medical Care 901 (2016).

[3] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015,* 65 Morbidity & Mortality Wkly. Rep. 1445 (2016); Substance Abuse and Mental Health Servs. Admin., U.S. Dep't of Health and Human Servs., *National Survey on Drug Use and Health, 2015 Detailed Tables* (2016).

[4] *See* Joanna G. Katzman et al, Rules and Values: A Coordinated Regulatory and Educational Approach to the Public Health Crises of Chronic Pain and Addiction, 104 Am. J. Pub. Health 1356 (2014); Ctrs. for Disease Control and Prevention, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999–2008,* 60 Morbidity & Mortality Wkly. Rep. 1487 (2011); Douglas C. McDonald at al., *Geographic Variation in Opioid Prescribing in the U.S.*, 13 J. Pain 988 (2012).

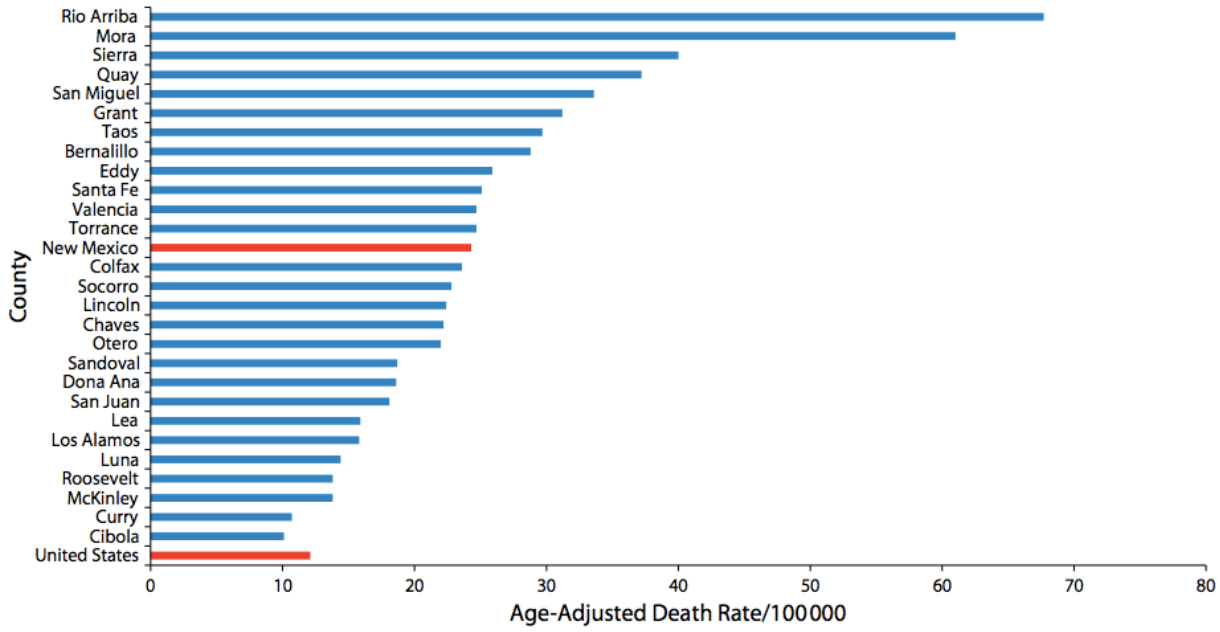


FIGURE 1—Drug overdose death rates by County: New Mexico, 2008–2012, and US, 2010.

5. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[5]

6. ***Hydrocodone*** is the most frequently prescribed opioid in the United States and is associated with more drug abuse and diversion than any other licit or illicit opioid. Its street names include Hydro, Norco, and Vikes. It is an orally active agent most frequently prescribed for the treatment of moderate to moderately severe pain. There are numerous brand and generic hydrocodone products marketed in the United States. The most frequently prescribed combination is hydrocodone and acetaminophen (for example, Vicodin®, Lorcet®, and Lortab®). Other examples of combination products include those containing aspirin (Lortab

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

ASA®), ibuprofen (Vicoprofen®) and antihistamines (Hycomine®). Most often these drugs are abused by oral rather than intravenous administration.[6]

7. ***Oxycodone*** is a semi-synthetic narcotic analgesic and historically has been a popular drug of abuse among the narcotic abusing population. Its street names include Hillbilly Heroin, Kicker, OC, Ox, Oxy, Perc, and Roxy. Oxycodone is marketed alone as OxyContin® in 10, 20, 40 and 80 mg controlled-release tablets and other immediate-release capsules like 5 mg OxyIR®. It is also marketed in combination products with aspirin such as Percodan® or acetaminophen such as Roxicet®. Oxycodone is abused orally or intravenously. The tablets are crushed and sniffed or dissolved in water and injected. Others heat a tablet that has been placed on a piece of foil then inhale the vapors.[7]

8. The State brings this suit against the manufacturers of these highly addictive drugs. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, turned patients into drug addicts for their own corporate profit.

9. The State also brings this suit against the wholesale distributors of these highly addictive drugs for breaching their legal duties under, *inter alia*, the New Mexico Controlled Substances Act, NMSA 1978, Sections 30-31-1 to -41 (1972, as amended through 2015) and 16.19.8.13 NMAC, to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

---

[6] *See* Drug Enf't Admin., *Drug Fact Sheet: Hydrocodone* (n.d.), https://www.dea.gov/druginfo/drug_data_sheets/Hydrocodone.pdf.

[7] *See* Drug Enf't Admin., *Drug Fact Sheet: Oxycodone* (n.d.), https://www.dea.gov/druginfo/drug_data_sheets/Oxycodone.pdf.

10. Defendants' conduct has exacted, and foreseeably so, a financial burden on the State of New Mexico. Categories of past and continuing damages sustained by the State include: (1) money wrongfully paid for opioids through government-funded insurance; (2) costs for providing medical care, additional therapeutic care, prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (3) costs for providing treatment, counseling, and rehabilitation services; (4) costs for providing treatment of infants born with opioid-related medical conditions; (5) costs for providing welfare for children whose parents suffer from opioid-related disability or incapacitation; and (6) costs associated with law enforcement and public safety relating to the opioid epidemic.

11. The State brings this action exclusively under the laws of the State of New Mexico. No federal claims are being asserted, and to the extent that any claim or factual assertion set forth herein may be construed to have stated any claim for relief arising under federal law, such claim is expressly and undeniably disavowed and disclaimed by the State.

12. Nor does the State bring this action on behalf of a class or any group of persons that can be construed as a class. The claims asserted herein are brought solely by the State and are wholly independent of any claims that individual users of opioids may have against Defendants.

II. PARTIES

A. Plaintiff

13. The State of New Mexico is a body politic created by the Constitution and laws of the State; as such, it is not a citizen of any state. This action is brought by the State in its sovereign capacity by and through Hector Balderas, the Attorney General of the State of New Mexico. Attorney General Balderas is acting pursuant to his authority under, *inter alia*, NMSA

1978, Sections 8-5-1 to -17 (1933, as amended through 1999); the New Mexico Unfair Practices Act, NMSA 1978, Sections 57-12-1 to -26 (1967, as amended through 2009); the New Mexico Racketeering Act, NMSA 1978, Sections 30-42-1 to -6 (1980, as amended through 2015); the New Mexico Medicaid Fraud Act, NMSA 1978, Sections 30-44-1 to -8 (1989, as amended through 2004); the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Sections 44-9-1 to -14 (2007, as amended through 2015); and New Mexico's public nuisance statutes, NMSA 1978, Sections 30-8-1 and -8 (1963).

B. Defendants

14. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times, each Defendant has occupied agency, employment, joint venture, or other relationships with each of the other named Defendants; that at all times herein mentioned each Defendant has acted within the course and scope of said agency, employment, joint venture, and/or other relationship; that each other Defendant has ratified, consented to, and approved the acts of its agents, employees, joint venturers, and representatives; and that each has actively participated in, aided and abetted, or assisted one another in the commission of the wrongdoing alleged in this Complaint.

15. At all relevant times Defendants, and each of them, have engaged in the business of, or were successors in interest to, entities engaged in the business of researching, licensing, designing, formulating, developing, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, distributing, and/or selling the prescription opioid drugs to individuals and entities in the State of New Mexico, including the City and County of Santa Fe, State of New Mexico.

16. At all relevant times, Defendants have sold and supplied opioid prescription drugs to individuals and entities located within every county of the State of New Mexico.

1. Manufacturer Defendants

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

18. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

19. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States and New Mexico. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers). Sales of Purdue's opioid drugs since the year 2000 have accounted for at least $7.6 million in reimbursements paid through the New Mexico Medicaid Program.

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

21. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States and New Mexico. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[8] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[9] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[10]

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

---

[8] *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.

[9] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

[10] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

23. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[11] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora®.[12] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

24. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its

---

[11] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last visited Aug. 21, 2017).

[12] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

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

25. Janssen manufactures, promotes, sells, and distributes drugs in the United States and New Mexico, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Since 2000, sales of Janssen's opioid products have accounted for at least $3.7 million in reimbursements paid through the New Mexico Medicaid Program.

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

27. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States and New Mexico. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana

ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States and New Mexico, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Since 2000, sales of Endo's opioid products have accounted for at least $1.7 million in reimbursements paid through the New Mexico Medicaid Program.

28. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is registered to do business with the New Mexico Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis

Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."

29. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States and New Mexico. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009. Sales of Actavis's opioid products have accounted for at least $9.7 million in reimbursements through the New Mexico Medicaid Program.

30. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware, and is registered with the New Mexico Secretary of State to do business in New Mexico. Since 2013, Mallinckrodt, LLC has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to 2013, Mallinckrodt, LLC was a wholly-owned subsidiary of the Irish public limited company Covidien pllc (formerly known as Tyco Healthcare). Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt." Since 2000, sales of Mallinckrodt's opioid products have accounted for at least $49 million in reimbursements paid through the New Mexico Medicaid Program.

31. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers, and opioids sold since at least June 2009 under the brand names Exalgo (hydromorphone), Xartemis (oxycodone/acetaminophen) and Roxicodone (oxycodone) (known by the street names "M," "roxies/roxys" or "blues"). In July 2017 Mallinckrodt agreed to pay $35 million to settle

allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

32. INSYS Therapeutics, Inc. (referred to here as "Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

33. Insys manufactures, promotes, sells, and distributes the opioid fentanyl also known as Subsys, in the United States, including in New Mexico. Subsys is a fentanyl sublingual (under the tongue) spray that has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[13] Subsys was Insys's only marketed product from March 2012 until July 2017. Insys revenues totaled over $240 million in 2016 and $330 million in 2015. Insys is a licensed pharmacy Controlled Substance Facility, wholesaler and distributor in the State of New Mexico.

2. Distributor Defendants

34. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription drug opioids, without fulfilling their fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes.

35. McKESSON CORPORATION, operated as a licensed pharmacy wholesaler in the State of New Mexico and is and was at all relevant times registered with the New Mexico Secretary of State as a Delaware corporation with its principal office located in San Francisco, California.

---

[13] *Highlights of Prescribing Information, SUBSYS® (fentanyl sublingual spray), CII* (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202788s016lbl.pdf.

36. CARDINAL HEALTH, INC. and its subsidiaries CARDINAL HEALTH 105, LLC; CARDINAL HEALTH 108, LLC; CARDINAL HEALTH 110, LLC; CARDINAL HEALTH 200, LLC; CARDINAL HEALTH 414, LLC; and CARDINAL HEALTH PHARMACY SERVICES, LLC; operated as licensed pharmacy wholesalers in the State of New Mexico and will be referred to collectively herein as "Cardinal Health."

37. Cardinal Health, Inc. is an Ohio corporation with its principal place of business in Dublin, Ohio.

38. Cardinal Health 105, LLC is an Ohio corporation with its principal place of business in Dublin, Ohio.

39. Cardinal Health 108, LLC is a Tennessee corporation with its principal place of business in Dublin, Ohio.

40. Cardinal Health 110, LLC is and was at all relevant times registered to do business with the New Mexico Secretary of State as a Delaware corporation with its principal place of business in Dublin, Ohio.

41. Cardinal Health 200, LLC is and was at all relevant times registered to do business with the New Mexico Secretary of State as a Delaware corporation with its principal place of business in Dublin, Ohio.

42. Cardinal Health 414, LLC is and was at all relevant times registered to do business with the New Mexico Secretary of State as a Delaware corporation with its principal place of business in Dublin, Ohio.

43. Cardinal Health Pharmacy Services, LLC is and was at all relevant times registered to do business with the New Mexico Secretary of State as a Delaware corporation with its principal place of business in Dublin, Ohio.

44. AMERISOURCEBERGEN DRUG CORPORATION, at all relevant times, operated as a licensed pharmacy wholesaler in the State of New Mexico and is and was registered to do business with the New Mexico Secretary of State as a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

III. JURISDICTION & VENUE

45. Subject matter jurisdiction for this case is conferred upon this Court pursuant to, *inter alia*, Article VI, Section 13 of the New Mexico Constitution.

46. This Court has personal jurisdiction over Defendants because Defendants do business in New Mexico and/or have the requisite minimum contacts with New Mexico necessary to constitutionally permit the Court to exercise jurisdiction with such jurisdiction also within the contemplation of the New Mexico "long arm" statute, NMSA 1978, Section 38-1-16 (1971).

47. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdiction of the Class Action Fairness Act of 2005. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the Complaint, as it sets forth herein exclusively viable state law claims against Defendants. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. No federal issue is important to the federal system as a whole under the criteria set by the Supreme Court in *Gunn v. Minton*, 568 U.S. 251 (2013) (*e.g.*, federal tax collection seizures, federal government bonds). Specifically, the causes of action asserted, and the remedies sought herein, are founded upon the positive statutory, common, and decisional laws of New Mexico. Further,

the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any exercise of federal jurisdiction is without basis in law or fact.

48. In this complaint, Plaintiff cites federal statutes and regulations. Plaintiff does so to state the duty owed under New Mexico tort law, *not* to allege an independent federal cause of action and *not* to allege any substantial federal question under *Gunn v. Minton.* "Generally, a negligence claim requires the existence of a duty from a defendant to a plaintiff, breach of that duty, which is typically based upon a standard of reasonable care, and the breach being a proximate cause and cause in fact of the plaintiff's damages." *Herrera v. Quality Pontiac*, 2003-NMSC-018, ¶ 6, 134 N.M. 43, 73 P.3d 181. With regard to the specifics of that duty, "[p]olicy determines duty." *Torres v. State*, 1995-NMSC-025, ¶ 9, 119 N.M. 609, 894 P.2d 386; *see also Calkins v. Cox Estates*, 1990-NMSC-044, ¶ 5, 110 N.M. 59, 792 P.2d 36 (stating that the question of duty "must be decided as a matter of law by the judge, using established legal policy"). That is, "[t]he existence of a tort duty is a policy question that is answered by reference to legal precedent, statutes, and other principles of law." *Herrera*, 2003-NMSC-018, ¶ 7 (internal citations omitted). To be clear, Plaintiff cites federal statutes and federal regulations for the sole purpose of stating the duty owed under New Mexico law to the citizens of New Mexico. Thus, the removal of this complaint based on an imagined federal cause of action or substantial question is without merit.

49. Venue is proper in this Court pursuant to NMSA 1978, Section 38-3-1 (1988), because the Office of the Attorney General and the seat of the State Government are situated in the City and County of Santa Fe, State of New Mexico, and the claims for relief asserted herein arose in large part in the City and County of Santa Fe, State of New Mexico.

IV. FACTUAL BACKGROUND

A. THE NATIONAL OPIOID EPIDEMIC

50. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.[14]

51. Prescription opioids became widely available in the mid-1990s. Between 1997 and 2007, per capita purchases of methadone, hydrocodone and oxycodone increased 13-fold, 4-fold, and 9-fold respectively. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[15]

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

> ■ The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
>
> ■ More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
>
> ■ Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
>
> ■ The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically

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

[15] Katherine M. Keyes at al., Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J. Pub. Health e52 (2014).

> according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
>
> ■ Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
>
> ■ Almost 5,500 people start to misuse prescription painkillers every day.[16]

53. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.[17]

54. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2014 there were almost 19,000 overdose deaths in the United States associated with prescription opioids.[18]

55. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[19]

56. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated

---

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

[17] *See* Califf et al., *supra* note 5.

[18] See id.

[19] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[20]

57. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use,*** specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.[21]

58. The societal costs of prescription drug abuse are "huge."[22]

59. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[23]

60. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[24]

---

[20] See Wilson M. Compton, Relationship Between Nonmedical Prescription-Opioid Use and Heroin, 374 N. Eng. J. Med. 154 (2016).

[21] *See* Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

[22] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter Brief of HDMA].

[23] See Rose A. Rudd et al., Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016).

61. In 2016, the President of the United States declared an opioid and heroin epidemic.[25]

62. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.[26]

B. NEW MEXICO'S OPIOID EPIDEMIC

63. New Mexico has been especially ravaged by the national opioid crisis.

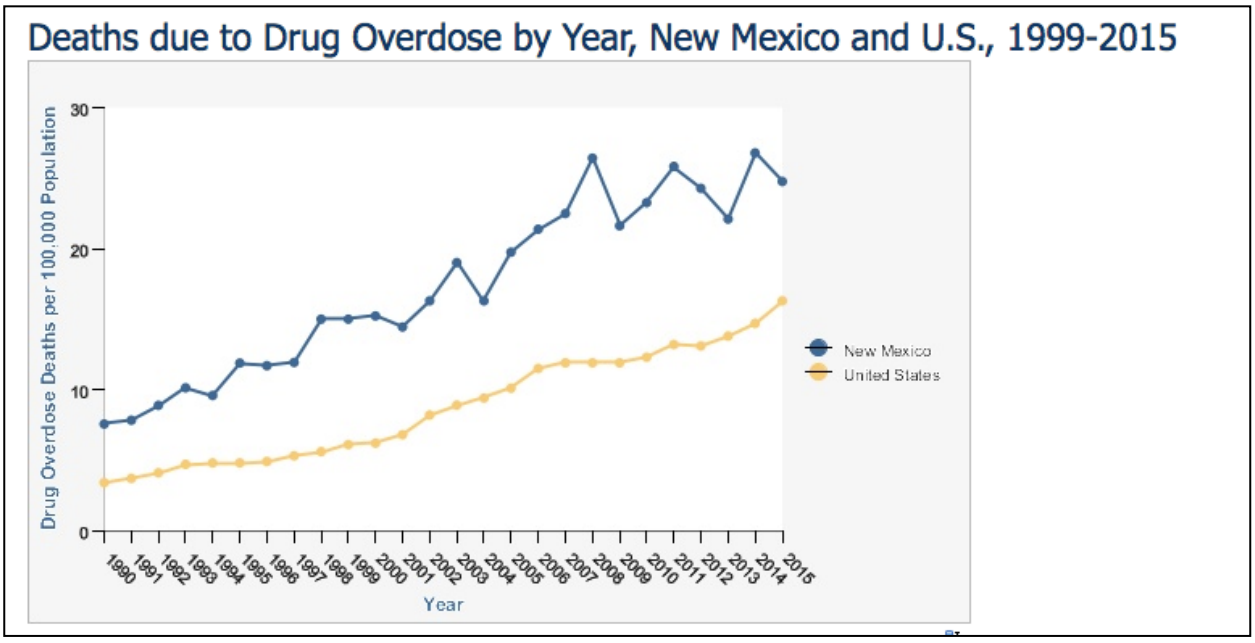
64. As reported by the New Mexico Department of Health, New Mexico's drug overdose rate has been one of the highest in the nation for most of the last two decades, far outpacing the national average:

---

[24] *See* Volkow & McLellan, *supra* note 1.

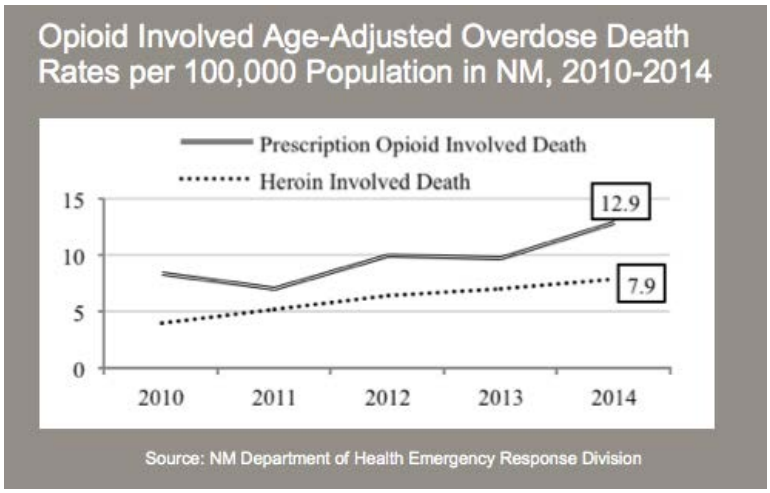
[25] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

[26] *See* Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf.



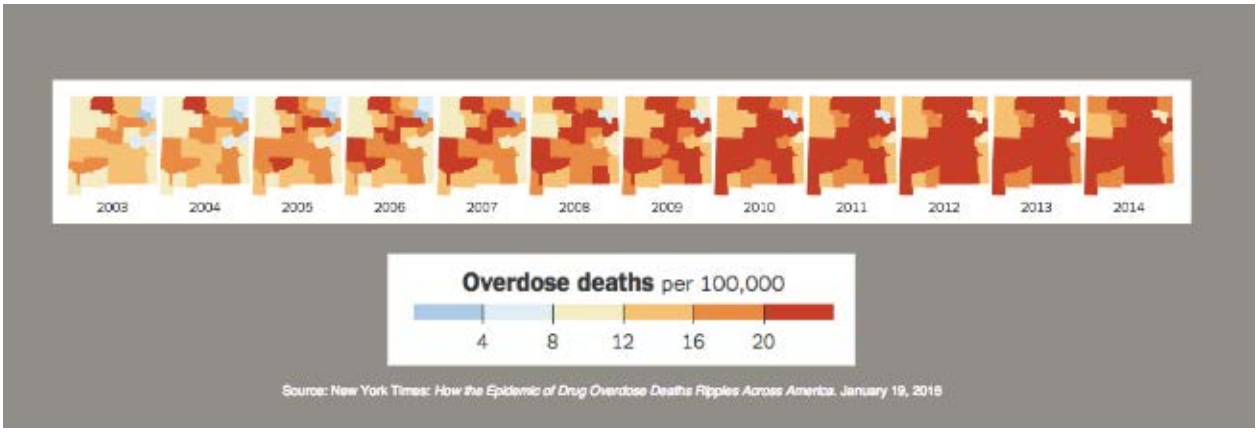
Source: New Mexico Dep't of Health, *New Mexico Substance Abuse Epidemiology Profile Report: Substance Abuse Epidemiology Profile for Drug Overdose Deaths* (2015), https://ibis.health.state.nm.us/report/saepi/summary/DrugOverdoseDth.html.

65. While deaths in New Mexico due to illicit drugs have remained steady for more than a decade, deaths due to prescription drugs (particularly opioid pain relievers) have increased dramatically. The number of drug overdose deaths in New Mexico involving opioid pain relievers or heroin nearly doubled between 2000 and 2014, from 196 deaths in 2000 to 382 in 2014. The number of overdose deaths involving prescription drugs exceeded the number involving illicit drugs in 2006, and by 2012, outnumbered illicit drug overdose deaths by 60%.



66. In 2014 alone, 547 New Mexicans died of a drug overdose, and 70% of those deaths (382) resulted from either opioid pain relievers or heroin. Of those deaths, 60% (229) involved prescription opioids without heroin, and another 10% (38) involved both prescription opioids and heroin.

67. New Mexico's death rate from drug overdose grew dramatically in lockstep with Defendants' increasing sale and distribution of opioid drugs:



Source: Haeyoun Park & Matthew Bloch, *How the Epidemic of Drug Overdose Deaths Ripples Across America*, N.Y. Times, Jan. 18, 2016, https://www.nytimes.com/interactive/2016/01/07/us/drug-overdose-deaths-in-the-us.html.

68. In New Mexico, the proportion of youth overdosing from heroin increased more than fivefold from 2004 through 2011. In 2011, New Mexico high school students were significantly more likely to have tried heroin or injected an illegal drug than high schoolers nationwide. And between 2002 and 2004 in Bernalillo County, youth between the ages of 18 and 25 sustained significantly higher rates of illicit use of prescription pain pills than individuals over age 25.[27]

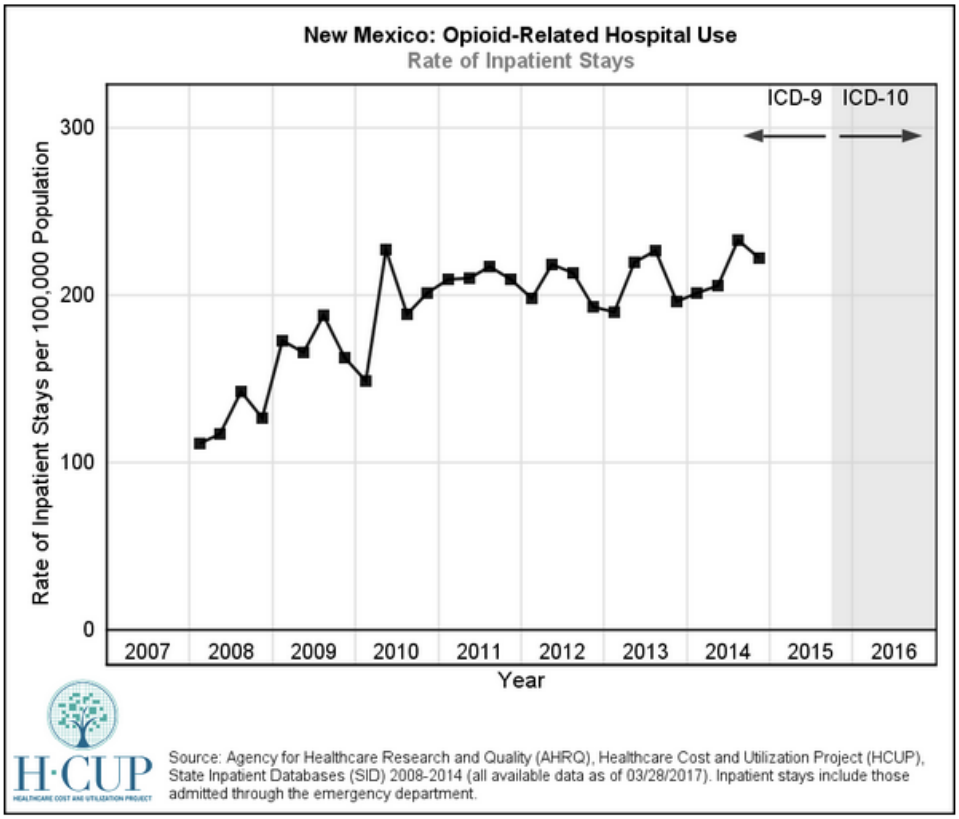
69. From 2000 through 2017, the New Mexico Medicaid Program spent at least $72.8 million for opioid pain medications.[28]

70. Based on the most current available data published by the New Mexico Prescription Monitoring Program, approximately 175,800 people in New Mexico are currently prescribed opioids.

71. Data maintained by the Agency for Healthcare Research and Quality for 2008 through 2014 document 27,450 in-patient hospital stays in New Mexico that are attributable to opioid-related hospital use. The annual rate of such stays per 100,000 population has continued to increase:

[27] Brenna L Greenfield et al., Opioid Use in Albuquerque, New Mexico: A Needs Assessment of Recent Changes and Treatment Availability, Addiction Sci. & Clinical Prac. June 18, 2014, at 1.

[28] *See* Ctrs. for Medicare & Medicaid Servs, U.S. Dep't of Health and Human Servs., *State Drug Utilization Data*, https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html (last visited Aug. 21, 2017). The State has not been able to identify all opioid drug reimbursements within this data set.



72. Between 2010 and 2015, the rate of opioid-overdose-related emergency department visits in New Mexico increased by almost 10%.[29]

73. From 2002 to 2011, admissions for treatment of non-heroin opiate abuse more than tripled at New Mexico's publicly-funded substance abuse treatment centers.[30] Annual admissions reached an average of 97 in the period from 2000 through 2004, but more than doubled that number by 2005 (196 admissions) and rose to 427 admissions during 2011.[31]

---

[29] New Mexico Dep't of Health, New Mexico Substance Abuse Epidemiology Profile Report: Health Indicator Report of Drug Overdose Deaths (2017) at 37.

[30] *See* Substance Abuse and Mental Health Servs. Admin., U.S. Dep't of Health and Human Servs., *Treatment Episode Data Set (TEDS) 2002-2012, State Admissions to Substance Abuse Treatment Services* 75 (2014), https://www.samhsa.gov/data/sites/default/files/2002-2012_TEDS_State/2002_2012_Treatment_Episode_Data_Set_State.pdf.

[31] *See id.*; Office of Applied Studies, Substance Abuse and Mental Health Servs. Admin., U.S. Dep't of Health and Human Servs., *Treatment Episode Data Set (TEDS) 1995-2005, National*

74. The New Mexico Department of Health estimates that **in 2007 alone** prescription opioid abuse, and misuse cost New Mexico $890 million, taking into account costs such as excess medical and prescription costs, lost earnings from premature deaths, and the costs of correctional facility and police services.[32]

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

75. The national opioid epidemic did not happen by accident.

76. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

77. By the late 1990s, and continuing today, each Manufacturer Defendant began a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to

---

Admissions to Substance Abuse Treatment Services 79 (2007), https://wwwdasis.samhsa.gov/dasis2/teds_pubs/2006_teds_rpt.pdf.

[32] New Mexico Dep't of Health, *New Mexico Substance Abuse Epidemiology Profile Report: Health Indicator Report of Drug Overdose Deaths* (2015), https://ibis.health.state.nm.us/indicator/view/DrugOverdoseDth.Year.NM_US.html.

spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

78. The Manufacturer Defendants made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

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

80. Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[33]

[33] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow,

In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[34] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

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

81. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in New Mexico. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State.

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

---

Drugmakers Hooked on $10bn Opioid Habit, Fin. Times, Aug. 10, 2016, https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[34] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.

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

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

a) Direct Marketing

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

85. A number of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for

each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

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

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

88. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated." Those materials in

particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."[35]

b) Indirect Marketing

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

90. The Manufacturer Defendants deceptively marketed opioids in New Mexico through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

91. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically

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

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

92. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

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

circumstances for long-term use – was untrue, and that the compassionate treatment of pain required opioids.

94. In 2007, several States including New Mexico sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. New Mexico settled its claims under the New Mexico Unfair Practices Act for Purdue's marketing practices prior to May 9, 2007, in a Consent Judgment that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future.[36] By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions.

95. In New Mexico, for example, the Manufacturers used their indirect marketing tactics to persuade the New Mexico Medical Board to offer two hours of continuing medical credits to doctors who read a publication sponsored by Cephalon and Purdue, *Responsible Opioid Prescribing* (2007), which misrepresented to doctors the risk of addiction associated with opioid usage and encouraged prescription practices that have worsened the opioid epidemic. To obtain CME credits for reading this publication, New Mexico doctors were required to submit a statement to their state licensing authority promising to "try to adopt its principles into my medical or surgical practice."

96. Similarly, as a result of the Manufacturer Defendants indirect marketing efforts, the State of New Mexico publicized industry-generated opioid prescribing tools to New Mexico health care providers in the State's 2011 "Clinical Guidelines on Prescribing Opioids for

[36] Stipulated Permanent Injunction and Final Judgment dated May 8, 2007, in *State of New Mexico ex rel. Gary King v. Purdue Pharma L.P., et al.*, No. D101 CV-2007-01094 in the First Judicial District, County of Santa Fe, New Mexico.

Treatment of Pain."[37] The State was unaware that those tools lacked a reliable scientific basis and would promote prescribing practices that worsened the opioid crisis in New Mexico.

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

98. Defendants utilized many KOLs, including many of the same ones.

99. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, Purdue, and Mallinckrodt (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first

[37] New Mexico Dep't of Health, *New Mexico Clinical Guidelines on Prescribing Opioids for Treatment of Pain* (2011), https://nmhealth.org/publication/view/general/271/.

in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

100. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in New Mexico and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[38]

101. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[39] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well . . . I guess I did."[40]

---

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

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

[40] *Id.*

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

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

104. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, the State of New Mexico publicized it to New Mexico Health Care Providers in the State's 2011 "Clinical Guidelines on Prescribing Opioids for Treatment of Pain."[41]

[41] New Mexico Dep't of Health, *New Mexico Clinical Guidelines on Prescribing Opioids for Treatment of Pain* (2011), https://nmhealth.org/publication/view/general/271/.

105. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach New Mexico doctors.[42]

106. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[43] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[44]

107. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored

---

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

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

[44] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

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

109. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[45]

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

[45] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

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

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

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

was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

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

114. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[46]

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

116. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top

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

of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon—and Mallinckrodt's then-parent, Covidien pllc—were members of the council and presented deceptive programs to doctors who attended this annual event.

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

118. The State is informed, and believes, that the Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

119. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole

consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[47]

120. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[48] Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Upon information and belief, pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

121. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[49] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee

[47] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

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

[49] Id.

members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in New Mexico during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants' financial support to members of the panel.

122. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

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

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

123. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described

below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, does not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

124. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use in New Mexico and continues to fail to correct its past misrepresentations.

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

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

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.[50]

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

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

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that

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

"[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

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

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[51]

h. In 2010, Mallinckrodt sponsored an initiative "Collaborating and Acting Responsibly to Ensure Safety" (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at www.defeatchronicpainnow.com, advises laypeople who are considering taking opioid drugs that "[o]nly rarely does opioid medication cause a true addiction."[52] Further, the book advises that even the issue of tolerance is "overblown," because "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance." In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that "[i]t is very uncommon for a person with chronic pain to become

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

[52] Charles E. Argoff & Bradley S. Galer, *Defeat Chronic Pain Now!* (2010).

'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

i. Upon information and belief, consistent with the Manufacturer Defendants' published marketing materials, detailers for Purdue, Endo, Janssen, Cephalon, and Mallinckrodt in New Mexico minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[53]

126. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[54] . The 2016 CDC Guideline further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid

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

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

use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[55].

127. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[56]

128. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[57] Endo had claimed on its

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

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

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

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

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

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

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.[58] The 2012

[58] Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2007) at 62.

edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[59]

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

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

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

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that

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

he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

a. In 2010, Mallinckrodt sponsored an initiative "Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at www.defeatchronicpainnow.com, teaches laypeople that "pseudoaddiction" is "caused by their doctor not appropriately prescribing the opioid medication." It teaches that "[p]seudoaddiction happens when a patient's opioid medication is not being prescribed in doses strong enough to provide good pain relief, or if the drug is not being prescribed often enough throughout the day. . . When a pseudoaddicted patient is prescribed the proper amount of opioid medication, he or she doesn't take any extra pills because his or her pain is relieved."

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

132. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug

screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

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

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

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

133. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."[60]

134. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturing Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.[61].

135. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[62] Similarly, in the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!", potential opioid users are advised that tolerance to opioids is "easily remedied," and that "[a]ll

[60] *Id.* at 11.

[61] *Id.* at 26.

[62] APF, *Policymaker's Guide*, *supra* note 51, at 32.

patients can be safely taken off opioid medication if the dose is slowly tapered down by their doctor."

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

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

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[63] This publication is still available online.

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

[63] APF, *Treatment Options*, *supra* note 50, at 12.

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."[64]

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

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

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.[65]

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

---

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

[65] APF, *Policymaker's Guide*, *supra* note 51, at 32.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.[66]

j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[67]

k. In the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!", potential opioid users are warned about the risk of "[p]seudoaddiction [b]ecause of a [l]ow [d]ose," and advised that this condition may be corrected through the prescription of a higher dose. Similarly, the book recommends that for chronic pain patients, the opioid dose should be "gradually increased to find the best daily dose, as is done with all the other oral drugs." The book discusses the risks of NSAIDs and other drugs at higher doses, but not explain this risk for opioids.

137. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[68] More specifically, the CDC explains that "there is now an established body of scientific evidence

[66] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited Aug. 21, 2017).

[67] Brief of APF, *supra* note 22, at 9.

[68] 2016 CDC Guideline, *supra* note 54, at 22–23.

showing that overdose risk is increased at higher opioid dosages."[69]The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[70] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[71]

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

139. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the product to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[72] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[73] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[74] Endo's own studies,

[69] *Id.* at 23–24.

[70] *Id.* at 21.

[71] *Id.* at 16.

[72] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

[73] *Id*. at 6.

[74] *Id*. at 6 n.21.

which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

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

140. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[75] The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

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

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

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

[75] *Id.* at 15.

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

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

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

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

g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."[76] This publication is still available online.

h. Upon information and belief, Endo's NIPC website "PainKnowledge" claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies,

[76] APF, *Treatment Options*, supra note 50.

that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[77] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

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

k. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[78] The Policymaker's Guide was originally published in 2011.

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

[77] *E.g.*, NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

[78] APF, *Policymaker's Guide*, *supra* note 51, at 29.

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

143. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[79]

144. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[80]Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is

[79] Letter from Thomas Abrams to Doug Boothe, *supra* note 35.

[80] 2016 CDC Guideline, *supra* note 54, at 12.

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

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

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

> OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications.

> For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.[81]

147. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.[82] Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are *opioid-tolerant*, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication."[83]

148. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, and for which it is not appropriate or safe. As part of this campaign,

---

[81] Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

[82] See U.S. Food & Drug Admin., Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.

[83] Id.

Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

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

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

- In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

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

150. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times,

Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.[84]

151. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

152. Insys deceptively marketed its opioid Subsys for chronic and mild pain even though the FDA has expressly limited its use to the treatment of severe cancer pain in opioid tolerant individuals. Subsys is an extremely powerful fentanyl-based sublingual opioid. It is not approved for, and has not been shown to be safe or effective for, chronic or mild pain. Indeed, the FDA expressly prohibited Insys from marketing Subsys for anything but breakthrough cancer pain in opioid tolerant patients.

---

[84] 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/.

153. Despite this, Insys conducted a well-funded campaign to promote Subsys for chronic pain and other non-cancer conditions for which it was not approved, not appropriate, and not safe. As part of this campaign, Insys used speaker programs, bribed doctors and tricked insurance companies into authorizing Subsys for treating non-cancer patients. For example:

- Upon information and belief, Insys aggressively marketed Subsys for uses not approved by the FDA, targeting doctors other than oncologists, including pills mills and pain clinics and promoting the drug for off-label uses like back and neck pain. Insys sought high-frequency opioid prescribers and pushed them to prescribe larger, more expensive doses.

- Upon information and belief, Insys set up a sham speaker program in which doctors – most of whom were not oncologists – were paid for speaking about Subsys at events where sign-in sheets were forged and the guests were often the speaker's friends and doctors who had already attended similar events. In turn, the speakers were expected to increase their prescriptions of Subsys. Insys also paid kickbacks and bribes to other physicians for increased prescription rates. Several healthcare providers have pled guilty to prescribing Subsys in exchange for kickbacks and many Insys employees and former employees – including the former CEO and former vice president of sales – have been charged criminally for the schemes, including bribing health care providers to unnecessarily prescribe Subsys.

- Upon information and belief, Insys set up a "reimbursement center" in which its employees called insurers and pharmacy benefit managers and falsely implied or stated that they were with the patient's health care provider calling to get prior authorization from the payor for the prescription. A prescription for Subsys requires preapproval from the insurance company because the drug is expensive and has such a limited use. Doctors' offices are supposed to confirm that the patient has cancer, is being treated with an opioid (so is opioid tolerant) and that the patient has unresolved breakthrough pain. The Insys employees, pretending to work for the doctor's office, falsely and intentionally implied or stated outright that the patient had cancer when the person did not.

- These practices allowed Insys to obtain a 42 percent share of the market for fentanyl-based opioid prescriptions, even though, upon information and belief, in 2016 only 7 percent of the Subsys prescriptions were written by oncologists.

- On information and belief, Insys is being investigated by the U.S. Department of Health and Human Services and at least 10 state attorneys general for actions related to its marketing of Subsys. Insys has already paid settlements to several states following allegations that they provided improper financial incentives to physicians and deceptively marketed Subsys for off-label use.

154. Insys's deceptive marketing gave doctors and patients the false impression that Subsys was not only safe and effective for treating chronic pain, but was also approved by the FDA for such uses.

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

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

156. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[85] The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.[86] The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

[85] 2016 CDC Guideline, *supra* note 54, at 13.

[86] *Id*. at 27.

4. The Manufacturing Defendants Fraudulently Concealed Their Misconduct.

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

158. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in

shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

159. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the State. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that the State now asserts. The State did not know of the existence or scope of the Manufacturer Defendants'

industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

D. THE DISTRIBUTOR DEFENDANTS' IRRESPONSIBLE DISTRIBUTION OF OPIOIDS

1. The Distributor Defendants Have a Duty to Guard Against, and Report, Unlawful Diversion.

160. The New Mexico Board of Pharmacy governs the licensing of wholesale drug distributors in this state. NMSA 1978, § 61-11-6(A)(6) (2005). Under New Mexico regulations, "[w]holesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs." 16.19.8.13(F)(1) NMAC.

161. In addition, "[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 16.19.20.48(A) NMAC. This same standard is promulgated in the criminal statues, specifically New Mexico's Controlled Substances Act. NMSA 1978, § 30-31-13(A)(1) (providing that "maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels" is a mandatory factor in board registration).

162. The New Mexico Controlled Substances Act and Administrative Code incorporate by reference relevant federal laws and regulations. 16.19.8.13(I) NMAC; NMSA 1978, §§ 30-31-13(C), 30-31-16(A). Therefore, "wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations." 16.19.8.13(I) NMAC. And, more specifically, "Wholesale drug distributors that deal in controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local and DEA regulations." 16.19.8.13(I)(2) NMAC. Moreover, the State's regulations are intended to conform to federal regulations barring any impracticality. NMSA 1978, § 26-1-18(A) (2005)

("The board shall conform the regulations promulgated under the New Mexico Drug, Device and Cosmetic Act, insofar as practical, with regulations promulgated under the federal act as defined in Section 26-1-2 NMSA 1978.").

163. Of particular import here, New Mexico regulations require that any diversion of a prescription drug be reported to the New Mexico Pharmacy Board, the FDA, and where applicable, to the DEA. 16.19.8.13(F)(5) NMAC ("Wholesale distributors shall report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and FDA and where applicable, to the DEA."). The same duty exists under federal regulations, which are incorporated by reference. *See* NMSA 1978, §§ 30-31-13(C), 30-31-16(A); 16.19.8.13(I) NMAC (incorporating by reference); 21 C.F.R. § 1301.74(b).[87] It is a crime to intentionally fail to furnish notifications required by the Controlled Substances Act and to intentionally omit any material information from any document required to be filed, or any record required to be kept, by the Act. NMSA 1978, §§ 30-31-24(A)(3).

164. Defendants have violated their duties under the New Mexico Controlled Substances Act and the New Mexico Administrative Code. *See* NMSA 1978, §§ 30-31-20, 30-31-24, 30-31-25; 16.19.8 NMAC; 16.19.20 NMAC.

165. Opioids are Schedule II controlled substances. NMSA 1978, § 30-31-7(A). As such, opioids are defined as substances that pose a high potential for abuse that may lead to severe dependence. NMSA 1978, § 30-31-5(B).

[87] To be crystal clear, Plaintiff cites federal statutes and federal regulations in this complaint to state the duty owed under New Mexico tort law, *not* to allege an independent federal cause of action or substantial federal question. *See, e.g.*, *Herrera*, 2003-NMSC-018, ¶7.

166. Defendants violated their duties as licensed wholesale distributors by selling huge quantities of opioids that were diverted from their lawful, medical purpose, thus causing an opioid and heroin addiction and overdose epidemic in this State.

167. As the DEA advised Defendants in a letter to them dated September 27, 2006, Defendants, as wholesale distributors, are "one of the key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[88]

168. Defendants violated New Mexico law when they violated a federal regulation that is incorporated into New Mexico law. 16.19.8.13(I) NMAC (which requires compliance with *inter alia* 21 C.F.R. § 1301.74(b)); NMSA 1978, §§ 30-31-13(C), 30-31-16(A); 16.19.20.49 NMAC ("Security requirements which meet the federal DEA provision shall be deemed adequate under New Mexico Controlled Substances Act."); *see also* NMSA 1978, § 26-1-18(A). Defendants thereby had a duty to disclose suspicious orders:

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

---

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

21 C.F.R. § 1301.74(b).[89] New Mexico law dictates the source of the duties owed. Therefore, even where a federal regulation informs some part of the case, that does not convert any state legal cause of action into any federal question, substantial or otherwise, because it is New Mexico law, and not any federal authority, that informs the existence of a duty.

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

[89] Once again, Plaintiff cites federal regulations in this complaint to state the duty owed under New Mexico tort law, *not* to allege an independent federal cause of action or substantial federal question. *See, e.g.*, *Herrera*, 2003-NMSC-018, ¶7.

170. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations carefully define each participant's role and responsibilities.[90]

171. The Defendant Wholesale Distributors have admitted that they are responsible for reporting suspicious orders.[91]

172. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, ***in addition*** to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[92] The letter also instructs that "distributors must be vigilant in deciding whether a prospective

---

[90] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS].

The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017).

The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/about/mission/ (last visited Aug. 21, 2017).

[91] *See* Brief for HDMA and NACDS, *supra* note 90, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[92] Rannazzisi Letter, *supra* note 88, at 2.

customer can be trusted to deliver controlled substances only for lawful purposes."[93] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[94]

173. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[95] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[96] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the

---

[93] *Id.* at 1.

[94] *Id.* at 2.

[95] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[96] Id.

particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

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

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[97]

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[98]

[97] Id.

[98] Id.

174. Defendants "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[99]

175. Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[100]

176. Each of the Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in New Mexico.

177. Each Defendant owes a duty under New Mexico law to monitor and detect suspicious orders of prescription opioids.

178. Each Defendant owes a duty under New Mexico law to investigate and refuse suspicious orders of prescription opioids.

---

[99] *See* Brief of HDMA, *supra* note 22, 2012 WL 1637016, at *2.

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

179. Each Defendant owes a duty under New Mexico law to report suspicious orders of prescription opioids, including suspicious orders originating outside New Mexico that would likely result in distribution of Defendants' opioids into New Mexico .

180. Each Defendant owes a duty under New Mexico law to prevent the diversion of prescription opioids into illicit markets in New Mexico.

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

182. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in New Mexico and the damages caused thereby.

2. Defendants Breached their Duties.

183. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[101]

184. The sheer volume of prescription opioids distributed to pharmacies in the State of New Mexico is excessive for the medical need of the community and facially suspicious. Some

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

red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[102]

185. The State is of the information and belief that the Distributor Defendants failed to report "suspicious orders" originating from New Mexico to the DEA, the New Mexico Department of Public Safety, and/or the New Mexico Board of Pharmacy.

186. The State alleges that the Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in New Mexico.

187. The Distributor Defendants illegally promoted the sale of dangerous and harmful drugs, in violation of the New Mexico Controlled Substances Act, Sections 30-31-1 to -41, by supplying suspicious orders for opiates to retail pharmacies, hospitals, and other health care facilities throughout the State of New Mexico that the Distributor Defendants knew were suspicious, including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

188. The laws at issue here, including *inter alia* NMSA 1978, Sections 30-8-1, 30-8-8, 30-31-25, 61-11-6, and 16.19.8.13 NMAC, and 16.29.20.48 NMAC, are public safety laws.

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

190. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the

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

DEA of suspicious orders when discovered, in violation of mandatory duties. *See* 16.19.8.13(I) NMAC; NMSA 1978, §§ 26-1-18(A), 30-31-13(C), 30-31-16(A). New Mexico law dictates the source of the duties owed. Therefore, even where a federal regulation informs some part of the case, that does not convert any state legal cause of action into any federal question, substantial or otherwise, because it is New Mexico law, and not any federal authority, that informs the existence of the duties owed.

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

192. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[103]

193. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from New Mexico.

194. The unlawful conduct by the Distributor Defendants is purposeful and intentional. Bluntly, they refuse to abide by the duties imposed by law which are required to maintain a New Mexico license to distribute prescription opiates.

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

> ■ The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders

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

(e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[104]

■ The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[105]

■ The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[106]

■ The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[107]

■ The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[108]

■ Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[109]

---

[104] Brief for HDMA and NACDS, *supra* note 90, 2016 WL 1321983, at *4–5.

[105] *Id.* at *8 (citations and quotation marks omitted).

[106] *Id.* at *14.

[107] *Id.* at *22.

[108] *Id.* at *24–25.

[109] *Id.* at 26.

196. The positions taken by the trade groups is emblematic of the position taken by the Defendant Wholesale Distributors in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[110]

197. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does in fact have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id*. at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all of the red flags giving rise to suspicious circumstance. *Id*. at 226. The Circuit Court also rejected the argument made by the Healthcare Distribution Management Association and National Association of Chain Drug Stores (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id*. at 220.

198. Wholesale Distributor McKesson has specifically admitted to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA

[110] *See* Brief of HDMA, *supra* note 22, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[111] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[112] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the [Controlled Substances Act] and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers" including the McKesson Distribution Center located in "Washington Courthouse, Ohio."[113] Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.[114]

199. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[115] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor

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

[112] *Id.* at 4.

[113] Id.

[114] *Id.* at 6.

[115] *Id.* at 4.

its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[116] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[117] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[118]

200. As a result of the decade-long refusal by the Distributor Defendants to abide by their legal obligations, the DEA has repeatedly taken administrative action to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[119] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[120] The public record reveals many of these actions:

> (a) On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007,

---

[116] Id.

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

[118] *See* 2017 Settlement Agreement and Release, *supra* note 117, at 6.

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

[120] Id.

AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

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

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

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

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

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

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

(h) On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida

Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

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

(j) On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

201. Rather than abide by these public safety statutes, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[121]

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

202. Meanwhile, the opioid epidemic rages unabated in New Mexico.

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

204. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement in New Mexico and abused the privilege of distributing controlled substances in our community.

3. The Distributor Defendants misled the State and the Public.

205. To protect their registered distributor status with *inter alia* the New Mexico Board of Pharmacy, the Distributor Defendants undertook efforts to fraudulently assure the public that they were complying with their obligations under licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

206. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[122] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or Cardinal Health had such a system, but it ignored the results.

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

207. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[123] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

208. Moreover, through their participation in the Healthcare Distribution Management Association ("HDMA"), the trade association of pharmaceutical distributors, the Distributor Defendants admit that they are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." Given Defendants' ability to know where opioids are being sent and how order volumes change year after year, they are well aware of their ability to identify suspicious sales volumes and patterns, but nonetheless chose not to report or take any actions to abate suspicious activity.

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

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

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

210. The Manufacturing Defendants were required to comply with the same licensing and permitting requirements as the Distributor Defendants. *See* NMSA 1978, § 30-31-13 (requiring manufacturers and distributors to register under the New Mexico Controlled Substances Act); § 16.19.8.2 NMAC **(**including manufacturers within the scope of the New Mexico wholesale distributing regulations); § 16.19.20.8 NMAC (requiring annual registration by manufacturers and distributors).

211. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under New Mexico law. *See, e.g.,* 16.19.20.48 NMAC; 16.19.8.13(F)(5) NMAC. Like the Distributor Defendants, the Manufacturer Defendants breached these duties.

212. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

213. New Mexico law requires that all registered distributors and manufacturers "shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 16.19.20.48 (A) NMSA; *see also, e.g.*, NMSA 1978, § 30-31-13(A)(1). The federal statutes and regulations incorporated into New Mexico law are equally clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).[124]

214. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[125]

215. The settlement arose from allegations that Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. In the press release accompanying the settlement, the Department of Justice stated: "These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and

[124] To be crystal clear, Plaintiff cites federal statutes and federal regulations in this complaint to state the duty owed under New Mexico tort law, *not* to allege an independent federal cause of action or substantial federal question. *See, e.g.*, *Herrera*, 2003-NMSC-018, ¶7.

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

distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[126]

216. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[127]

217. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[128]

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

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. conduct adequate due diligence of its customers;

[126] Id.

[127] Id.

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

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

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

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

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

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

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

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[129]

219. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 C.F.R. 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt

[129] 2017 Mallinckrodt MOA at p. 2-3.

agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[130]

220. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[131]

221. The same duties imposed by New Mexico law on Mallinckrodt were imposed upon all Manufacturer Defendants.

222. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

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

224. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by New Mexico law.

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

---

[130] *Id.* at 3-4.

[131] *Id.* at p.5.

226. The Manufacturer Defendants have misrepresented their compliance with New Mexico law.

227. The Manufacturer Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

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

229. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into New Mexico and into areas surrounding New Mexico from which opioids were illicitly diverted into New Mexico.

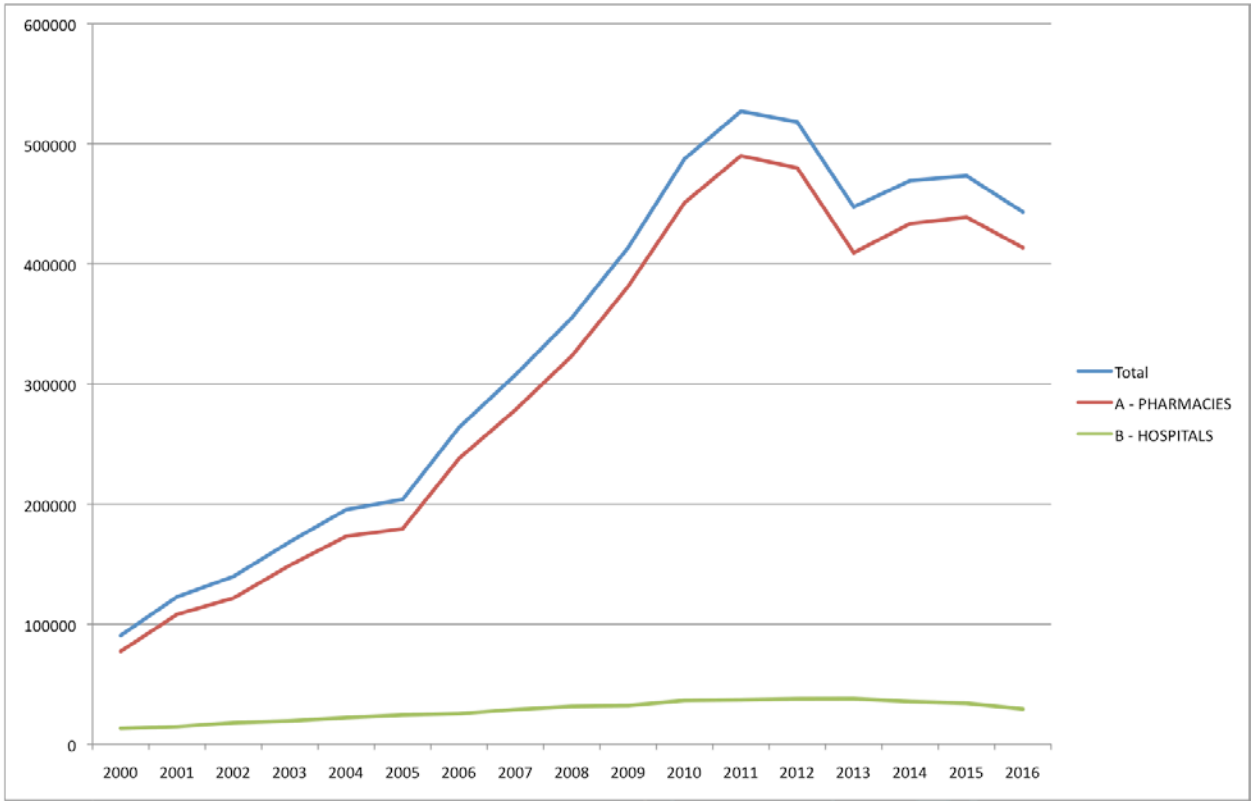
F. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED SUBSTANTIAL DAMAGES.

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

231. Retail drug shipment data made publicly available by the Drug Enforcement Agency shows that shipments of OxyContin into New Mexico increased in volume by 580% between 2000 and 2011, with shipments to retail pharmacies—which are more likely to supply

painkillers for treatment of chronic pain—increasing substantially, while shipments to hospitals remained fairly constant:

OxyContin Retail Shipments to New Mexico, 2000-2016
(Grams shipped)



Source: Drug Enforcement Administration, ARCOS Retail Drug Summary Reports, Report 5.

232. Shipments of Hydrocodone (e.g., Vicodin, Lortab) to New Mexico more than tripled in the same period, again with the increase coming almost entirely from shipments to retail pharmacies rather than hospitals. Total shipments of fentanyl (which includes Duragesic) and morphine each increased two-and-a-half times from 2001 to 2011, following the same pattern.

233. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[132]

234. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[133]

235. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[134]

236. The increased use of prescription painkillers for nonmedical reasons (without a prescription for the high they cause), along with growing sales, has contributed to a large number of overdoses and deaths.[135]

237. As discussed above in paragraphs 58 through 69, New Mexico has experienced a substantial increase in the rates of opiate-related substance abuse, hospitalization and death that mirrors Defendants' increased distribution of opiates.

238. Given the well-established relationship between the use of prescription opiates and the use of heroin, the State is informed and believes, and based thereon alleges, that the increase in opiate usage in the State of New Mexico is dramatically increasing the rate of heroin addiction among New Mexico residents.

239. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in New Mexico.

---

[132] *See* Dart at al., *supra* note 14.

[133] *See* Volkow & McLellan, *supra* note 1.

[134] *See* Califf et al., *supra* note 5.

[135] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra* note 10.

240. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in New Mexico.

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

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

243. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[136]

244. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.[137]

245. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."[138]

246. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the State of New Mexico.

---

[136] *See* Rudd et al., *supra* note 23, at 1445.

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

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

G. TOLLING OF THE STATUTE OF LIMITATIONS

247. Generally speaking, the statute of limitations does not run against the State. Independently, any allegedly applicable limitations period is tolled.

1. Continuing Conduct

248. Plaintiff, State of New Mexico, contends it continues to suffer harm from the unlawful actions by the Defendants.

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

2. Equitable Estoppel

250. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State of New Mexico, that they were undertaking efforts to comply with their obligations under the Controlled Substances Act, Sections 30-31-1 to -41, all with the goals of protecting their registered manufacturer or distributor status in the State and of continuing to generate profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State of New Mexico, that they were working to curb the opioid epidemic.

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

efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[139]

252. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[140]

253. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[141]

- "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
- "DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."
- "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

[139] Bernstein et al., *supra* note 121.

[140] Higham et al., *supra* note 123.

[141] Brief for HDMA and NACDS, *supra* note 90, 2016 WL 1321983, at *3-4, *25.

- "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."
- "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

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

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

255. The State reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

3. Fraudulent Concealment

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

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

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

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

V. LEGAL CAUSES OF ACTION

COUNT I
PUBLIC NUISANCE
NMSA 1978, § 30-8-8-1 and common law
(Against all Defendants)

260. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

261. The Attorney General may bring an action to abate a public nuisance in the name of the State. NMSA 1978, § 30-8-8(B).

262. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of thousands of New Mexico residents and interferes with the enjoyment of life in violation of New Mexico law.

263. Prescription opioid abuse, addiction, morbidity, and mortality are a temporary public nuisance in New Mexico, which remains unabated. The unlawful conduct by the Defendants has created these hazards to public health and safety.

264. The health and safety of the citizens of the State, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the State's citizens and residents.

265. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit.

266. Defendants knew, or should have known, that their promotion and irresponsible distribution of opioids (in violation of their monitoring and reporting obligations) would create a public nuisance.

267. Defendants are liable for a public nuisance because they acted without lawful authority in knowingly creating and maintaining opioid use at such volumes and degree as to create an epidemic, which clearly affects a number of citizens, is injurious to public health, safety, morals and welfare, and interferes with the exercise and enjoyment of public rights. NMSA 1978, § 30-8-1.

268. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public. *City of Albuquerque v. State ex rel. Village of Los Ranchos de Albuquerque*, 1991-NMCA-015, ¶ 17, 111 N.M. 608, 808 P.2d 58 ("A public nuisance is a wrong that arises by virtue of an unreasonable interference with a right common to the general public.") (citing Restatement (Second) of Torts § 821B(1); further cit. om.). The Defendants' conduct described herein significantly interferes with public health, safety, peace, comfort, and convenience. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

269. In addition and independently, Defendants' conduct invades a legally protected interest. Defendants' conduct constitutes an unreasonable interference because *inter alia* each Distributor Defendant has violated New Mexico law. §§ 30-31-1 to -41; § 61-11-6; 16.19.8.13 NMAC, 16.19.20.48 NMAC. The Distributor Defendants have permitted dangerous drugs under their control to be diverted for illicit purposes such as to injure the State and its residents.

270. The Manufacturer Defendants have violated New Mexico law. §§ 30-31-1 to -41; § 30-16-6. The Manufacturer Defendants conducted a fraudulent campaign to misrepresent the safety and efficacy of opioid drugs and to ensure their widespread use for chronic pain knowing that Defendants were specifically misrepresenting the high risk of severely harmful addiction.

271. Because Defendants have maintained their opioid drug selling activities contrary to law, and because Defendants' conduct has unreasonably interfered with a right common to the general public, Defendants are liable for public nuisance per se. *See Espinosa v. Roswell Tower,*

Inc., 1996-NMCA-006, ¶ 10, 121 N.M. 306, 910 P.2d 940 ("An activity conducted or maintained contrary to law may be a public nuisance per se when the activity unreasonably interferes with a right common to the general public.").

272. Defendants' unreasonable interference with a right common to the public is of a continuing nature.

273. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the State of New Mexico. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under New Mexico law as substances posing a high potential for abuse and severe addiction. NMSA 1978, §§ 30-31-5(B), 30-31-7(A). Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

274. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Distributor Defendants' abdication of their gate-keeping duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is not limited to:

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

b. Nor have children escaped the opioid epidemic unscathed. Easy access to prescription opioids made opioids a recreational drug of choice among New Mexico teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those State residents who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. The opioid epidemic has increased health care costs.

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

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

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

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

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

j. Defendants' interference with the comfortable enjoyment of life in New Mexico is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

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

276. Plaintiff, the State of New Mexico, seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, abatement of the public nuisance, payment to the State of monies necessary to abate the public nuisance, all damages as allowed by law, attorney fees and costs, and pre- and post-judgment interest.

COUNT II
VIOLATION OF NEW MEXICO UNFAIR PRACTICES ACT
(NMSA 1978, §§ 57-12-1 to -26)

277. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

278. At all times relevant herein, the Defendants violated the New Mexico Unfair Practices Act, §§ 57-12-1 to -26, by committing repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in the conduct of commerce, both of which are violations of the Act.

279. The Attorney General is authorized to bring an action in the name of the State to remedy violations of the Unfair Practices Act. NMSA 1978, §§ 57-12-8(A), 57-12-15. This action is proper in this Court because Defendants are using, have used, and are about to use practices that are unlawful under the Act. NMSA 1978, § 57-12-8(A).

280. Because Defendants' irresponsibly marketed and distributed opioid drugs were diverted to non-medical purposes, these drugs had no value.

281. Defendants' actions and transactions are forbidden by the New Mexico Board of Pharmacy, which is a regulatory body, and therefore Defendants' actions and transactions are subject to the Unfair Practices Act. NMSA 1978, § 57-12-7.

282. As alleged herein, each Distributor Defendant violated the Unfair Practices Act by failing to report and/or prevent the diversion of highly addictive prescription drugs to illegal sources. This was an unconscionable trade practice that took advantage of New Mexico patients and addicts to their detriment and to a grossly unfair degree. NMSA 1978, § 57-12-2(E)(1).

283. Because of the dangerously addictive nature of these drugs, the Distributor Defendants' lax distribution practices unlawfully caused an opioid and heroin plague and epidemic in New Mexico. Each Distributor Defendant had a non-delegable duty to guard against

and prevent the diversion of opioid pills to other than legitimate medical, scientific, and industrial channels. As illegally diverted, the opioid pills lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' distribution of opioids constituted unconscionable trade practices under NMSA 1978, § 57-12-2(E)(2), in that Defendants' practices resulted in a gross disparity between value received (i.e., none) and price paid.

284. The Distributor Defendants also committed unfair or deceptive trade practices because they omitted material facts. *See* NMSA 1978, § 57-12-2(D)(14); *see also* § 57-12-2(D)(2) (causing confusion or misunderstanding as to approval or certification of goods or services) and § 57-12-2(D)(15) (stating that a transaction involves rights it does not involve).

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

286. As alleged herein, each Manufacturer Defendant, at all times relevant to this Complaint, violated the Unfair Practices Act by committing unfair or deceptive trade practices as defined in the Unfair Practices Act by representing that the opioid prescription pills "have … characteristics, … uses, [or] benefits … that they do not have." NMSA 1978, § 57-12-2(D)(5).

287. The Manufacturer Defendants also committed unfair or deceptive trade practices by representing that the opioids were safe and effective when such representations were untrue, false, and misleading in violation of Section 57-12-2(D)(7).

288. The Manufacturer Defendants also used exaggeration and/or ambiguity as to material facts and omitted material facts, which had a tendency to deceive and/or did in fact deceive. NMSA 1978, § 57-12-2(D)(14).

289. The Manufacturer Defendants also committed unconscionable trade practices that took advantage of New Mexico patients and addicts to their detriment and to a grossly unfair degree. NMSA 1978, § 57-12-2(E)(1).

290. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted unconscionable trade practices under Section 57-12-2(E)(2), in that Defendants' practices resulted in a gross disparity between value received (i.e., none) and price paid.

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

292. On or after May 8, 2007, Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following:

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

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

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

unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

293. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

294. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

295. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

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

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

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

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

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

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

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

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

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

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

296. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

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

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

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

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

297. Defendant Mallinckrodt made and/or disseminated deceptive statements, including, but not limited to, the following:

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

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

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

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

298. Defendant Insys made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

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

b. Providing significant financial support to doctors who increased the dosage amount and number of prescriptions they made for Subsys;

c. Directing its marketing of Subsys to a wide range of doctors who were not oncologists, and promoting the drug for off-label uses like back and neck pain;

d. Making deceptive statements concerning the use of Subsys to treat chronic non-cancer pain to prescribers throughout the United States—including, upon information and belief, New Mexico prescribers—through in-person detailing and speakers bureau events, when such uses are unapproved and unsafe; and

e. Making deceptive statements to insurers and pharmacy benefit managers, including misrepresenting that they were the patients' health care provider calling to get prior authorization from the payor for the prescription, and falsely and intentionally implying or stating that the patient had cancer when the patient did not.

299. Defendants' unfair, deceptive, and unconscionable representations, concealments, and omissions were reasonably calculated to deceive the State, the New Mexico Board of Pharmacy and New Mexico consumers, were made with the intent to deceive the State, New Mexico Board of Pharmacy and New Mexico consumers, and did in fact deceive the State, the New Mexico Board of Pharmacy, and New Mexico consumers, who paid for prescription opioids for chronic pain.

300. As described more specifically above, Defendants' representations, concealments, and omissions constitute a willful course of conduct which continues to this day. Unless enjoined from doing so, the Manufacturer and Distributor Defendants will continue to violate the New Mexico Unfair Practices Act.

301. But for these deceptive representations and concealments of material fact and material omissions, New Mexico consumers would not have incurred millions of dollars in damages, including without limitation the costs of harmful drugs.

302. As a direct and proximate cause of the Manufacturer and Distributor Defendants' unfair or deceptive and/or unconscionable trade practices, New Mexico and New Mexico consumers have been injured in an amount to be determined at trial.

303. Defendants' unfair, deceptive and unconscionable trade practices are willful and subject to $5,000 civil penalty for each and every violation per each Defendant. NMSA 1978, § 57-12-11.

304. Each exposure of a New Mexico resident to opioids resulting from the aforementioned conduct of each and all Defendants constitutes a separate violation of the Unfair Trade Practices Act.

305. Each and every prescription written in New Mexico without an adequate warning constitutes a separate violation of the Unfair Practices Act on the part of the Manufacturer Defendants.

306. Each and every prescription filled by the Distributor Defendants constitutes a separate violation of the Unfair Practices Act on the part of the Distributor Defendants.

307. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to the Manufacturer Defendants' misleading and deceptive information regarding opioids, including *inter alia* through print information, websites, presentations, brochures, or packaging constitutes a separate violation pursuant to the Unfair Practices Act.

308. Plaintiff, State of New Mexico, seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, abatement, reimbursement of all monies paid for prescription opioids by the State of New Mexico, restitution for all monies paid for opioids in connection with State of New Mexico programs and/or by state agencies and/or departments,

damages as allowed by law, all recoverable penalties under Section 57-12-11 including a civil penalty of $5,000 per each violation per each Defendant named in this Count, attorney fees and costs, and pre- and post-judgment interest.

COUNT III
VIOLATION OF NEW MEXICO
MEDICAID FRAUD ACT
NMSA 1978, §§ 30-44-1 to -8.
(Against All Defendants Except Insys)

309. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

310. Pursuant to NMSA 1978, Section 30-44-7(A), Medicaid fraud consists of, *inter alia*:

> (3) presenting or causing to be presented for allowance or payment with intent that a claim be relied upon for the expenditure of public money any false, fraudulent, excessive, multiple or incomplete claim for furnishing treatment, services or goods; or
>
> (4) executing or conspiring to execute a plan or action to:
>
> > (a) defraud a state … funded or mandated managed health care plan in connection with the delivery of or payment for health care benefits, including engaging in any intentionally deceptive marketing practice in connection with proposing, offering, selling, soliciting or providing any health care service in a state or federally funded or mandated managed health care plan; or
> >
> > (b) obtain by means of false or fraudulent representation or promise anything of value in connection with the delivery of or payment for health care benefits that are in whole or in part paid for or reimbursed or subsidized by a state or federally funded or mandated managed health care plan. This includes representations or statements of financial information, enrollment claims, demographic statistics, encounter data, health services available or rendered and the qualifications of persons rendering health care or ancillary services.

311. Manufacturer Defendants, through their deceptive marketing of opioids for chronic pain, presented or caused to be presented for payment false or fraudulent claims, with

intent that the claims be relied upon for the expenditure of funds from the New Mexico Human Services Department, Medical Assistance Division.

312. Manufacturer Defendants defrauded New Mexico health care plans by engaging in intentionally deceptive marketing practices in connection with the sale of opioid prescription pills.

313. Manufacturer Defendants knew, at the time of making or disseminating the deceptive statements discussed herein, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of selling increasing amounts of opioids to be paid for by the New Mexico Human Services Department, Medical Assistance Division. In addition, Defendants knew that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain. Defendants also knew that their deceptive marketing practices would result in the New Mexico Human Services Department, Medical Assistance Division paying for prescription opioid pills that were used for illegitimate, unnecessary, non-medical purposes.

314. The Manufacturer Defendants' scheme caused doctors to write prescriptions for opioids that were paid for by the New Mexico Human Services Department, Medical Assistance Division.

315. As described above and expressly incorporated herein, the Distributor Defendants misrepresented their compliance with their legal obligations to maintain a closed system. The Distributor Defendants failed to maintain effective controls against diversion of opioids and failed to monitor, detect and report suspicious orders of prescription opioids.

316. The Distributor Defendants periodically and systematically misrepresented – either affirmatively or through half-truths and omissions – to the general public, the State, and the New Mexico Board of Pharmacy – that they were fulfilling the requirements of their New Mexico wholesale distributor licenses when, in fact, they were neglecting their duty to prevent the diversion of opioids for non-medical purposes in pursuit of ever-increasing profits. The Distributor Defendants obtained, by means of these false and fraudulent representations, payment for opioid drugs prescribed to New Mexico Medicaid recipients.

317. As a result of the Manufacturer Defendants' intentionally deceptive marketing of opioids, and the Distributor Defendants unlawfully and fraudulently lax distribution of opioids, the New Mexico Medicaid program has paid millions of dollars for these pills. As a result, Defendants have been illegally enriched at the expense of the New Mexico Medicaid program. Further, the New Mexico Medicaid program has been required and will be required to pay the costs of treatment for Medicaid recipients harmed by Defendants' actions.

318. The Manufacturer Defendants' aggressive, illegal promotions have induced a misallocation of State Medicaid funds through a pattern of fraudulent conduct. Defendants made or caused false or fraudulent claims, statements and representations of material fact to be made in connection with the New Mexico Medicaid program. The Manufacturing Defendants' scheme included the implementation of intentionally deceptive marketing practices. Defendants intended that their fraudulent promotion be relied upon or result in the expenditure of public money, and lead to the reimbursement of prescriptions by the New Mexico Medicaid program.

319. The Manufacturer and Distributor Defendants' wrongful conduct resulted in charges to the New Mexico Medicaid program for goods or services that were illegitimate, illicit

and not medically necessary, and which would not have been approved for payment by the New Mexico Medicaid program had these facts been known.

320. Each claim submitted for opioid prescriptions for payment by the New Mexico Medicaid program constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

321. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to misleading and deceptive information regarding opioids, including *inter alia* through print information, websites, presentations, brochures, or packaging constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

322. As a direct and proximate result of Defendants' wrongful conduct, the State of New Mexico and its citizens have suffered and will continue to suffer substantial damage and injury as a result of Defendants' violations of the New Mexico Medicaid Fraud Act.

323. Plaintiff, State of New Mexico, seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, abatement and damages as allowed by law, reimbursement of all monies paid for opioids in connection with the New Mexico Medicaid Program, a civil penalty of three times the amount of excess payments, a civil penalty of ten thousand dollars ($10,000) for each false or fraudulent claim submitted or representation made, attorney fees and all other costs of investigation and enforcement of civil remedies, and pre- and post-judgment interest.

COUNT IV
RACKETEERING ACT
NMSA 1978, §§ 30-42-1 to -6
(Against All Defendants Except Insys)

324. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

325. The State, both as a "person" who has sustained injury ***and*** on behalf of New Mexico citizens who have been injured, brings this claim for civil remedies under the Racketeering Act, NMSA 1978, Sections 30-42-1 to -6, against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "Racketeering Defendants"). The Attorney General has the specific statutory authority to bring this action pursuant to NMSA 1978, Sections 30-42-5, 30-42-6.

326. The Racketeering Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the Racketeering Defendants were "persons" under NMSA 1978, § 30-42-3(B) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

327. Section 30-42-4 of the Racketeering Act makes it unlawful "for any person employed by or associated with any enterprise to conduct or participate, directly or indirectly, in the conduct of the enterprise's affairs by engaging in a pattern of racketeering activity." NMSA 1978, § 30-42-4(C).

328. The term "enterprise" is defined as including "a sole proprietorship, partnership, corporation, business, labor union, association or other legal entity or a group of individuals

associated in fact although not a legal entity and includes illicit as well as licit entities." NMSA 1978, § 30-42-3(C).

329. For over a decade, the Racketeering Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Racketeering Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the Racketeering Defendants operated and continue to operate within the nationwide "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the "CSA") and the New Mexico Controlled Substances Act, NMSA 1978, Sections 30-31-1 to -41. Together, the CSA and New Mexico Controlled Substances Act restrict the Racketeering Defendants' ability to manufacture or distribute Schedule II substances like opioids nationally and in New Mexico by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA, the New Mexico Pharmacy Board, and the FDA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

330. The nationwide closed system, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids

from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."[142]

331. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their duty under New Mexico law to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA, the New Mexico Board of Pharmacy, and the FDA of suspicious orders.[143] As discussed in detail below, through the Racketeering Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas throughout the United States for opioids allowed by the DEA.[144] In doing so, the Racketeering Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

332. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the Racketeering Defendants were associated with, and conducted or participated in, the affairs of the racketeering enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, and to deceive the public, and federal and state regulators into

[142] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[143] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

[144] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

believing that the Racketeering Defendants were faithfully fulfilling their statutory obligations. The Racketeering Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Racketeering Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the State of New Mexico experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the Racketeering Defendants' misconduct violated Section 30-42-4 of the Racketeering Act and the State is entitled to treble damages for its injuries under Section 30-42-6(A).

333. Alternatively, the Racketeering Defendants were members of a legal entity enterprise within the meaning of NMSA 1978, Section 30-42-3(B) through which the Racketeering Defendants conducted their pattern of racketeering activity in New Mexico and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")[145] is a distinct legal entity that satisfies the definition of a racketeering enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in Section 30-42-3(B) because it is a corporation and a legal entity.

[145] Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

334. On information and belief, each of the Racketeering Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

335. Each of the Racketeering Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the Racketeering Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Racketeering Defendants exists separately from the HDA. Therefore, the HDA may serve as a racketeering enterprise.

336. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the Racketeering Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

A. THE OPIOID DIVERSION ENTERPRISE

337. Throughout the United States—and within the State of New Mexico—the Racketeering Defendants have operated at all relevant times under a "closed distribution system" of quotas that governs the production and distribution of prescription opioid drugs. The Opioids Diversion Enterprise is an ongoing and continuing business organization that created and maintained systemic links for a common purpose: To protect and maximize their profitability under this quota system through the unlawful sale of opioids. The Racketeering Defendants participated in the Opioids Diversion Enterprise through a pattern of racketeering activity, which includes multiple violations of New Mexico state criminal law.

338. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States

Congress enacted the Controlled Substances Act in 1970.[146] The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.[147] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[148] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."[149] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[150] Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[151] All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent

[146] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2, February 10, 2012).

[147] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

[148] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

[149] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

[150] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[151] See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf).

diversion.[152] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[153] The result is the scourge of addiction that has occurred.

339. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."[154] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the United States Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw

[152] *Id.*; 16.19.8.13(F)(5) NMAC (requiring anyone licensed to distribute Schedule II controlled substances in New Mexico to "report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and FDA and where applicable, to the DEA."); 16.19.20.48(A) NMSA ("All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.")

[153] Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

[154] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[155]

340. Under the CSA, as incorporated into New Mexico law, it is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[156]

341. At all relevant times, the Racketeering Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their duty under New Mexico law to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, *see generally* **IV.D.1** and **IV.E**, *supra*, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Racketeering Defendants conducted their pattern of racketeering activity in New Mexico and throughout the United States through this enterprise.

342. The Racketeering Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the Racketeering Defendants were filling on a daily basis -- leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

---

[155] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[156] *Id.* (citing 21 U.S.C. 842(b)); 16.19.8.13(I)(2) NMAC (registrants authorized to distribute controlled substances in New Mexico "shall register with the [New Mexico Pharmacy] board and with the DEA, and shall comply with all applicable state, local and DEA regulations").

343. The Racketeering Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and illegal trafficking in and distribution of prescription opioids, in violation of New Mexico law.

344. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding reports and representations about their systems for controlling against diversion, and refusal to report suspicious orders.

345. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, nationwide per capita purchases of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the county with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[157] On information and belief, the Opioid Diversion Enterprise has been ongoing nationally and in New Mexico for at least the last decade.[158]

346. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But, it was not until recently that State and federal regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public and the State of New Mexico and its citizens.

---

[157] Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. Am J Public Health. 2014;104(2):e52-9.

[158] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

347. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each Racketeering Defendant; (b) was separate and distinct from the pattern of racketeering in which the Racketeering Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Racketeering Defendants; (d) characterized by interpersonal relationships among the Racketeering Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Racketeering Defendants would have a larger pool of prescription opioids from which to profit.

348. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there may be some legitimate uses and/or needs for prescription opioids, the Racketeering Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase

and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

349. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the Racketeering Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

350. Each of the Racketeering Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The Racketeering Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the Racketeering Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

351. The Racketeering Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum ("PCF"), the HDA, and through their contractual relationships.

352. PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

353. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[159] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[160] In New Mexico, when the Legislature considered proposals to address the State's prescription opioid epidemic in 2012, PCF members registered at least six additional lobbyists and doubled their donations to New Mexico political campaigns.[161]

354. Not surprisingly, each of the Racketeering Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[162] In 2012, membership and participating organizations included the HDA (of which all Racketeering Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (*i.e.*, Allergan), and Teva (the parent company of Cephalon).[163] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade

[159] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (emphasis added).

[160] Id.

[161] Id.

[162] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf .

[163] *Id*. The State is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

organization, the HDA.[164] The State is informed and believes that the Distributor Defendants participated directly in the PCF as well.

355. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers, Pyles, Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

356. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

357. Second, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the Racketeering Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon, were members of the

[164] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/executive-committee.

HDA.[165] The HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

358. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[166] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Distributors.

359. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Racketeering Defendants.[167] The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its

---

[165] Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer.

[166] Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.

[167] Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[168]

360. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."[169]

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.[170]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.[171]

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.[172]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state

[168] Id.

[169] Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/councils-and-committees.

[170] Id.

[171] Id.

[172] Id.

legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.[173]

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[174]

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[175]

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.[176]

i. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[177]

361. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

362. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing

[173] Id.

[174] Id.

[175] Id.

[176] Id.

[177] Id.

industry issues."[178] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[179] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[180]

363. Third, the Racketeering Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

364. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[181] As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the

---

[178] Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.

[179] Id.

[180] 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

[181] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.mccaskill.senate.gov/opioid-investigation; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), http://www.purduepharma.com/payers/managed-markets/.

HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[182] On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[183] The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

365. The contractual relationships among the Racketeering Defendants also include vault security programs. The Racketeering Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates.[184] The State is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. The State is informed and believes that these agreements were used by the Racketeering Defendants as a tool to violate their reporting and diversion duties under New Mexico law, in order to reach the required sales requirements.

366. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation

[182] Id.

[183] Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

[184] *See, e.g.*, 16.19.20.48 (B)(6) NMAC (factors considered in evaluating whether registrants maintain effective controls against diversion include "the type of vault, safe, and secure enclosures or other storage system used").

between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Racketeering Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrate that the leaders of each of the Racketeering Defendants were in communication and cooperation.

367. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum – whose members include the Manufacturers and the Distributors' trade association – has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."[185] From 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.[186] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[187]

368. As described above, the Racketeering Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to further the common purpose of their

[185] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

[186] Id.

[187] HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/hda-history.

enterprise. The State is informed and believes that the Racketeering Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

369. The Racketeering Defendants conducted the Opioids Diversion Enterprise, and participated in the enterprise, by engaging in a pattern of racketeering activity, as prohibited by NMSA 1978, 30-42-4(C).

370. During the time period alleged in this Complaint, the Racketeering Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their obligations under New Mexico law (and federal law, as incorporated into New Mexico law) to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales as set forth below. In doing so, the Racketeering Defendants increased production quotas and generated unlawful profits.

371. The Racketeering Defendants disseminated statements that were false and misleading – either affirmatively or through half-truths and omissions – to the general public, the State, New Mexico consumers, and the New Mexico Board of Pharmacy, claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

372. The Racketeering Defendants disseminated statements that were false and misleading – either affirmatively or through half-truths and omissions – to the general public, the State, New Mexico consumers, and the New Mexico Board of Pharmacy, claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

373. The Racketeering Defendants disseminated statements that were false and misleading – either affirmatively or through half-truths and omissions – to the general public, the State, New Mexico consumers, and the New Mexico Board of Pharmacy claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

374. The Opioid Diversion Enterprise worked to scale back regulatory oversight by the DEA that could interfere with the Racketeering Defendants' ability to distribute their opioid drugs in the State of New Mexico. To distribute controlled substances in New Mexico, the Racketeering Defendants had to be able to demonstrate possession of a current DEA registration. *See* 16.19.20.14 NMAC(B). Even if they held a current registration, the Racketeering Defendants' ability to obtain a New Mexico registration could be jeopardized by past suspension or revocation of their DEA registration. 16.19.20.14 NMAC(A)(6).

375. The Racketeering Defendants paid nearly $800 million dollars to influence local, state and federal governments throughout the United States and in New Mexico, through joint lobbying efforts as part of the Pain Care Forum. The Racketeering Defendants were all members of the Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids—protecting the Racketeering Defendants' ability to distribute prescription opioids in New Mexico.

376. The Racketeering Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

377. The Racketeering Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[188]

378. The Racketeering Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. The State is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, the State is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

379. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the Racketeering Defendants.

---

[188] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

380. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Racketeering Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[189] On information and belief, the "know your customer" questionnaires informed the Racketeering Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

381. The Racketeering Defendants refused to identify, investigate and report suspicious orders to the DEA, the New Mexico Board of Pharmacy, and the FDA when they became aware of the same despite their actual knowledge of drug diversion rings. The Racketeering Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[190] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause

[189] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/ levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

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

and 41 actions involving immediate suspension orders – all for failure to report suspicious orders.[191]

382. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and to identify suspicious orders and report them to the DEA and State governments, including the State of New Mexico.

383. The Racketeering Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and to ensure that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids as required by New Mexico law, the Racketeering Defendants ensured that the DEA had no basis for refusing to increase, or to decrease, the production quotas for prescription opioids due to diversion of suspicious orders. The Racketeering Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

[191] Id.

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."[192]

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The Racketeering Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The Racketeering Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

[192] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

j. The Racketeering Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

384. The scheme devised and implemented by the Racketeering Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, in intentional violation of New Mexico law, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY

385. The Racketeering Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in NMSA 1978, Section 30-42-3 (D), by multiple predicate acts indictable as fraud (NMSA 1978, § 30-16-6), trafficking in controlled substances (NMSA 1978, § 30-31-20), and distribution of controlled substances or controlled substance analogues (NMSA 1978, §§ 30-31-21 to -22), and punishable by imprisonment of at least one year, with the intent of accomplishing activities prohibited by Section 30-42-4 of the Racketeering Act.

386. The Racketeering Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of NMSA 1978, §§ 30-16-6, 30-31-21, and 30-31-22), within a five-year period. The multiple acts of racketeering activity that the Racketeering Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Racketeering Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise.

387. The Racketeering Defendants committed these predicate acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the Opioids Diversion Enterprise by conducting activities prohibited by NMSA 1978, Section 30-42-4.

388. The predicate acts all had the purpose of generating significant revenue and profits for the Racketeering Defendants while the State was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Racketeering Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme. The predicate acts were related and not isolated events.

389. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, the Racketeering Defendants are distinct from the enterprise.

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

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

392. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in the State of New Mexico. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase

and maintain their increased profits, without regard to the effect such behavior would have on New Mexico, New Mexico consumers, or other New Mexico citizens. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Racketeering Defendants were also aware that the State and the citizens of this jurisdiction rely on the Racketeering Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

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

394. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by New Mexico law, would harm the State by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

395. The Racketeering Defendants did not undertake the predicate acts described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Racketeering Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Racketeering Defendants.

396. The Racketeering Defendants aided and abetted others in the violations of NMSA 1978, Sections 30-16-6, 30-31-21, and 30-31-22, while sharing the same criminal intent as the

principals who committed those violations, thereby rendering them indictable as principals in the offenses.

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

1. The Racketeering Defendants Conducted the Opioid Diversion Enterprise through Acts of Fraud in Violation of NMSA 1978, § 30-16-6.

398. "Fraud consists of the intentional misappropriation or taking of anything of value that belongs to another by means of fraudulent conduct, practices or representations." NMSA 1978, § 30-16-6.

399. The Racketeering Defendants' fraudulent conduct, practices, and representations include, but are not limited to:

a. Misrepresentations to facilitate Defendants' DEA registrations, which were a predicate to their registrations with the New Mexico Board of Pharmacy;

b. Requests for higher aggregate production quotas, individual production quotas, and procurement quotas to support Defendants' manufacture and distribution of controlled substances they knew were being or would be unlawfully diverted;

c. Misrepresentations and misleading omissions in Defendants' records and reports that were required to be submitted to the DEA pursuant to 16.19.8.13.I(2) NMAC (requiring compliance with all applicable state, local and DEA regulations, including 21 U.S.C. § 827);

d. Misrepresentations and misleading omissions in documents and communications related to the Defendants' mandatory DEA reports pursuant to 16.19.8.13.I(2) NMAC (requiring compliance with all applicable state, local and DEA regulations, including 21 U.S.C. § 823 and 21 C.F.R. § 1301.74); and

e. Rebate and chargeback arrangements between the Manufacturers and the Distributors that Defendants used to facilitate the manufacture and sale of controlled substances they knew were being or would be unlawfully diverted.

400. Specifically, the Racketeering Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report

suspicious orders of prescription opioids and/or diversion of the same into the illicit market, all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Racketeering Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

401. At the same time, the Racketeering Defendants misrepresented the superior safety features of their order monitoring programs, their ability to detect suspicious orders, their commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

402. The Racketeering Defendants intended to and did, through the above-described fraudulent conduct, practices, and representations, intentionally misappropriate funds from the State and from private insurers, in excess of $500, including, for example:

a. Costs of prescriptions provided under New Mexico's Medicaid Program;

b. Public employees' health insurance prescription coverage costs pursuant to the Group Benefits Act, NMSA 1978, Section 10-7B-6 (2006);

c. Retired public employees' group insurance costs from the Retiree Health Care Fund, pursuant to the Retiree Health Care Act, NMSA 1978, Section 10-7C-8 (1990);

d. Public employees and school board retirees' group health insurance costs from the Public School Insurance Fund, pursuant to the Public School Insurance Authority Act, NMSA 1978, Sections 22-29-1 to -12 (2003, as amended through 2011); and

e. Prescription benefits paid by private insurers for opioid prescriptions.

403. Many of the precise dates of the fraudulent acts and practices have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But,

the State has described the types of, and in some instances, occasions on which the predicate acts of fraud occurred.

2. The Racketeering Defendants Unlawfully Trafficked in and Distributed Controlled Substances in Violation of NMSA 1978, §§ 30-31-20 to -22.

404. Defendants' racketeering activities also included violations of the New Mexico Controlled Substances Act, Section 30-31-20 to -22, and each act is chargeable or indictable under the laws of New Mexico and punishable by imprisonment for more than one year. *See* NMSA 1978, § 30-42-3(A)(13) (defining controlled substance trafficking as racketeering); § 30-42-3(A)(19) (defining controlled substance distribution as racketeering).

405. Under New Mexico law (NMSA 1978, § 30-31-20 to 22), it is unlawful to "intentionally traffic"—i.e., to manufacture, distribute, sell, or possess with intent to distribute—prescription opioids, which are Schedule II controlled substances that are narcotic drugs, except as authorized by the New Mexico Controlled Substances Act.

406. The Racketeering Defendants intentionally trafficked in prescription opioid drugs, in violation of New Mexico law, by manufacturing, selling, and/or distributing those drugs in New Mexico in a manner not authorized by the New Mexico Controlled Substances Act. The Racketeering Defendants failed to act in accordance with the New Mexico Controlled Substances Act because they did not act in accordance with registration requirements as provided in that Act. *See* NMSA 1978, §§ 30-31-12(B), 30-31-13(C), 30-31-16(A); 30-31-24(A)(2)-(3), and 30-31-25(A)(4).

407. Among other infractions, the Racketeering Defendants did not comply with 21 U.S.C. § 823 and its attendant regulations (*e.g.*, 21 C.F.R. § 1301.74),[193] which are incorporated into New Mexico state law, or the New Mexico Pharmacy Board regulations. The Racketeering Defendants failed to furnish notifications required under the New Mexico Controlled Substances Act. NMSA 1978, § 30-31-24(A)(3). Relatedly, the Racketeering Defendants omitted required reports. NMSA 1978, § 30-31-25)(A)(4).

408. The State is informed and believes that the Racketeering Defendants failed to furnish required notifications and make reports as required by New Mexico law as part of a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA, as required by 21 C.F.R. § 1301.74, throughout the United States.

409. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[194]

410. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of their duty to report suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet

[193] Once again, Plaintiff cites federal statutes and federal regulations in this complaint to state the duty owed under New Mexico tort law, *not* to allege an independent federal cause of action or substantial federal question. *See, e.g.*, *Herrera*, 2003-NMSC-018, ¶7.

[194] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017), http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/.

failed to alert the DEA.[195] The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[196] Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[197]

411. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.[198] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.[199]

---

[195] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

[196] Id.

[197] Id.

[198] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

[199] Id.

412. The Racketeering Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports is evident in the sheer volume of enforcement actions available in the public record against the Distributor Defendants.[200] For example:

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

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

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

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

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

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

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related

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

to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

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

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

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

413. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

414. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

D. DAMAGES

415. The Racketeering Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the State of New Mexico and its citizens injury in their business and property because the State paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

416. The State's injuries, and those of its citizens, were proximately caused by Defendants' racketeering activities. But for the Racketeering Defendants' conduct, the State would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

417. The State's injuries and those of its citizens were directly caused by the Racketeering Defendants' racketeering activities.

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

419. The State of New Mexico seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit (NMSA 1978, § 30-42-6), and pre- and post-judgment interest.

COUNT V
CONSPIRACY TO VIOLATE RACKETEERING ACT
NMSA 1978, §§ 30-42-1 to -6.
(Against All Defendants except Insys)

420. The State hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

421. The State brings this claim on behalf of itself and its citizens against all Racketeering Defendants.

422. At all relevant times, the Racketeering Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate NMSA 1978, Section 30-42-4(C), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity. Under Section 30-42-4(D), it is unlawful for "any person to conspire to violate" Section 30-42-4(C), among other provisions.

423. Defendants conspired to violate Section 30-42-4(C), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

A. THE OPIOID DIVERSION ENTERPRISE

424. For efficiency and avoiding repetition, for purposes of this claim, the State incorporates by reference the paragraphs set out above concerning the "Opioid Diversion Enterprise."

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

425. For efficiency and avoiding repetition, for purposes of this claim, the State incorporates by reference the paragraphs set out above concerning the "Conduct of the Opioid Diversion Enterprise."

C. PATTERN OF RACKETEERING ACTIVITY

426. For efficiency and avoiding repetition, for purposes of this claim, the State incorporates by reference the paragraphs set out above concerning the "Pattern of Racketeering Activity."

D. DAMAGES

427. The Racketeering Defendants' conspiracy to violate the Racketeering Act proximately caused the State of New Mexico and its citizens injury in their business and property

because the State paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

428. The State's injuries, and those of its citizens, were proximately caused by the Racketeering Defendants' conspiracy to violate Section 30-42-4(C) of the Racketeering Act. But for the Racketeering Defendants' conduct, the State would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

429. The State's injuries and those of its citizens were directly caused by the Racketeering Defendants' conspiracy to violate Section 30-42-4(C). The State was most directly harmed and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

430. The State of New Mexico seeks all legal and equitable relief as allowed by law, including inter alia actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit (NMSA 1978, § 30-42-6), and pre- and post-judgment interest.

COUNT VI
VIOLATION OF NEW MEXICO
FRAUD AGAINST TAXPAYERS ACT
NMSA 1978, §§ 44-9-1 -14
(Against All Defendants)

431. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

432. Defendants' willful and repeated conduct related to opioid sales, as described above, violates the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Section 44-9-3.

433. As detailed above, the Manufacturer Defendants willfully misrepresented opioids as an appropriate, beneficial, and non-addictive treatment for chronic pain, and Defendants'

course of conduct caused the State of New Mexico to pay for drugs that were worthless in that they had no beneficial value, and in fact, were harmful to patients.

434. The Distributor Defendants secured and renewed licenses from *inter alia* the New Mexico Board of Pharmacy under false pretenses when, in fact, the Distributor Defendants were not abiding by their non-delegable legal duties. As further described above, the Distributor Defendants made false public statements representing that they were operating a closed system safeguarding against diversion of dangerous opioids into illicit channels when, in truth, the Distributor Defendants were ignoring their legal duties for profit.

435. Each Defendant knowingly presented, or caused to be presented, to the State false or fraudulent claims for payment or approval, in violation of NMSA 1978, Section 44-9-33A(1).

436. Each Defendant knowingly made, used, or caused to be made or used, false, misleading or fraudulent statements or records to obtain or support the approval of, or the payment on, false or fraudulent claims, in violation of NMSA 1978, Section 44-9-33A(2).

437. By engaging in the wrongful conduct described herein, Defendants conspired to defraud the State by obtaining approval or payment on false or fraudulent claims.

438. As a result of the Manufacturer Defendants' fraudulent marketing of opioids, and the Distributor Defendants' abdication of non-delegable duties to prevent opioids from being diverted into illicit channels, the State of New Mexico paid millions of dollars for opioids. As a result, Defendants were illegally enriched at the expense of the State of New Mexico. Further, the State of New Mexico was required and will be required to pay the costs of treatment for State of New Mexico participants actively harmed by the Defendants' actions.

439. Each claim for opioid prescriptions presented to the State of New Mexico or to a contractor, grantee or other recipient of state funds constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

440. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional or State of New Mexico participant to Defendants' misleading and deceptive information, communicated in any manner by Defendants, constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

441. In addition to, or in the alternative, each opioid prescription written in New Mexico in connection with State of New Mexico programs constitutes a separate and distinct violation pursuant to NMSA 1978, Section 44-9-3.

442. Plaintiff, State of New Mexico seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, civil penalties of not less than $5,000 and up to $10,000 for each violation, attorney fees and all costs and expenses of suit, and pre- and post-judgment interest.

COUNT VII
NEGLIGENCE
NEW MEXICO COMMON LAW
(Against All Defendants)

443. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

444. A negligence claim requires the existence of a duty from a defendant to a plaintiff, breach of that duty, which is typically based upon a standard of reasonable care, and the breach being a proximate cause and cause in fact of the plaintiff's damages. *Herrera*, 2003-NMSC-018, ¶7.

445. Each Defendant had an obligation to exercise reasonable care in manufacturing and distributing highly dangerous opioid drugs in the State of New Mexico.

446. Integral to duty and proximate causation is foreseeability. *Id.* ¶8. Each Defendant owed a duty to the State, and to the public health and safety in New Mexico, because the injury was foreseeable, and in fact foreseen, by the Defendants.

447. Reasonably prudent wholesale drug distributors would have anticipated that the scourge of opioid addiction would wreak havoc on communities. As explained above, the system whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies exists ***for the purpose*** of controlling dangerous substances such as opioids. Moreover, Defendants were repeatedly warned by law enforcement.

448. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

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

450. As described above in language expressly incorporated herein, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting

harm – diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

451. As described above in language expressly incorporated herein, Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain. The causal connection between Defendants' breach of duties and ensuing harm was entirely foreseeable.

452. As described above in language expressly incorporated herein, Defendants' breach of duty caused, bears a causal connection with, and/or proximately resulted in, harm and damages to the State.

453. Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent. Here, Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. NMSA 1978, § 30-31-5(B). Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels.

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

COUNT VIII
NEGLIGENCE PER SE
NEW MEXICO COMMON LAW
(Against Distributor Defendants)

455. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

456. NMSA 1978, Section 26-1-18, 16.19.8.13 NMAC, and 16.19.20.48 NMAC, are public safety laws. As such, these laws were intended to protect the public welfare and safety, and the State is the proper Plaintiff to enforce these laws. Each Distributor Defendant had a duty under *inter alia* these laws to prevent diversion of prescription opioids for non-medical and non-scientific purposes and to guard against, prevent, and report suspicious orders of opioids.

457. The Distributor Defendants' violations of the law constitute negligence per se.

458. It was foreseeable that the breach of duty described herein would result in the damages sustained by the State.

459. Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent, as described above.

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

461. As described above in language expressly incorporated herein, the Distributor Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, and proximately resulted in, harm and damages to the State. The harm at issue is the type of harm that the legislature sought to prevent in promulgating the public safety statutes at issue.

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

PUNITIVE DAMAGES

463. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

464. By engaging in the above-described unfair acts or practices, Defendants acted wantonly or oppressively or with such malice as implies a spirit of mischief or criminal indifference to civil obligations. Defendants' conduct also was willful, reckless, and/or fraudulent. *See Clay v. Ferrellgas, Inc.*, 1994-NMSC-080, ¶ 12, 118 N.M. 266, 881 P.2d 11 ("To be liable for punitive damages, a wrongdoer must have some culpable mental state, . . . and the wrongdoer's conduct must rise to a willful, wanton, malicious, reckless, oppressive, or fraudulent level . . . .") (citations omitted).

465. Here, Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. NMSA 1978, § 30-31-5(B). Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the State by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over patients, and the safety of the community, and an award of punitive damages is appropriate, as punishment and as deterrence.

466. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

RELIEF

WHEREFORE, the State of New Mexico, by and through its Attorney General, respectfully prays that this Court grant the following relief:

1. Entering Judgment in favor of the State in a final order against each of the Defendants;

2. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in unfair or deceptive practices in violation of New Mexico law and ordering temporary, preliminary or permanent injunction;

3. Order that Defendants compensate the State for its past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

4. Declaring that each act and omission of each of the Defendants described in this Complaint constitute multiple, separate violations of the Unfair Practices Act;

5. Imposing civil penalties of up to $5,000, per Defendant, for each repeated and willful violation of the Unfair Practices Act;

6. Awarding actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to the Racketeering Act;

7. Imposing civil penalties of not less than $10,000 per Defendant under the Medicaid Fraud Act, for each false or fraudulent claim submitted or representation made, plus

three times the amount of damages that the State has sustained as a result of the act of Defendants;

8. Awarding actual damages, treble damages, and civil penalties of not less than $5,000 and up to $10,000 for each violation of the Fraud Against Taxpayers Act;

9. Awarding the State its past and future damages caused by the opioid epidemic, including (A) money wrongfully paid for opioids through government-funded insurance; (B) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (C) costs for providing treatment, counseling, and rehabilitation services; (D) costs for providing treatment of infants born with opioid-related medical conditions; (E) costs for providing welfare for children whose parents suffer from opioid-related disability or incapacitation; and (F) costs associated with law enforcement and public safety relating to the opioid epidemic.

10. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

11. Granting the State:

a. The cost of investigation, reasonable attorneys' fees, and all costs and expenses;

b. Pre-judgment and post-judgment interest; and,

c. All other relief as provided by law and/or as the Court deems appropriate and just.

Plaintiff asserts claims herein in excess of the minimum jurisdictional requirements of this Court.

Dated: December 20, 2017

Respectfully submitted,

ATTORNEY GENERAL OF NEW MEXICO
HECTOR H. BALDERAS

P.O. Drawer 1508
Santa Fe, NM 87504-1508
Phone: (505) 490-4060
Fax: (505) 490-4883
hbalderas@nmag.gov