

September 7, 2017

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Attorney General Balderas Files Lawsuit Against Opioid Manufacturers and Distributors for Fueling the Opioid Epidemic that is Crippling New Mexico

Albuquerque, NM - **Attorney General Hector Balderas** announced today that he has brought a lawsuit on behalf of the State of New Mexico against the country's largest manufacturers and wholesale distributors of opioids, a crucial first step toward holding these companies responsible for flooding New Mexico's communities with prescription opioids and fueling the opioid epidemic by putting profits over people. The State of New Mexico is filing suit against five of the largest manufacturers of prescription opioids and their related companies and against the country's three largest wholesale drug distributors. The manufacturing companies pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction, while the distributors breached their legal duties to monitor, detect, investigate, refuse and report suspicious orders of prescription opioids.

"New Mexico continues to endure the most catastrophic effects of the opioid crisis, all while major out of state corporations make billions in profits at the expense of our families and communities," said **Attorney General Hector Balderas**. "This lawsuit is part of my office's multi-pronged effort, Project OPEN, to combat the opioid crisis in New Mexico by holding drug manufacturers and distributors accountable, securing treatment resources, and increasing funding for law enforcement."

"I support Attorney General Balderas' continued efforts to combat the opioid epidemic, particularly in Rio Arriba County," **Española Mayor Alice Lucero** said. "Families in Española know all too well what the realities of this crisis look like and this action is much needed to stop the flood of these dangerous drugs into our community."

"As the District Attorney of communities with some of the highest opioid and heroin abuse rates in the country, I see the daily effects of this crisis in our own backyards," said **1st Judicial District Attorney Marco Serna**. "Attorney General Balderas' efforts to combat this problem are part of a crucial statewide solution, and are the only way rural communities will be protected from this epidemic. I helped Attorney General Balderas launch Project OPEN earlier this year and I will continue to partner with his office to combat this crisis as one jurisdiction cannot do it alone."

"The Doña Ana County District Attorney's Office supports Attorney General Balderas' lawsuit and leadership on this important issue, and I look forward to hosting the next Project OPEN with the Attorney General in Las Cruces," said **3rd Judicial District Attorney Mark D'Antonio**. "We must attack the opioid crisis that is ravaging our families and straining our law enforcement resources in Doña Ana County and across New Mexico."

Las Cruces Mayor Ken Miyagishima said, "The opioid crisis is spreading across New Mexico at an alarming rate and in Las Cruces we are working to get ahead of the epidemic by focusing on prevention and treatment. That is why I am proud to partner with Attorney General Balderas to host the next Project OPEN training in Las Cruces and to support his lawsuit seeking critical resources for New Mexico communities in this battle."

The lawsuit was filed in the First Judicial District Court in Santa Fe County. The lawsuit alleges, among numerous counts, that the drug manufacturers falsely and misleadingly downplayed the serious risk of addiction to prescription opioids and falsely touted the benefits of long-term opioid use, reversing the popular and medical understanding of opioids. The wholesale distributors, meanwhile, violated their duties 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 the State of New Mexico.

The opioid epidemic has grown worse as people addicted to prescription pills have-- thanks to heightened enforcement efforts--found them harder to come by. Very often, these individuals have turned to cheaper, illegal street drugs including heroin and fentanyl. The residents of New Mexico continue to bear the burden of the epidemic as the costs of health care, addiction treatment, education, and law enforcement have continued to rise.

While deaths in New Mexico due to illicit drugs have remained steady during the past 10 years, deaths due to prescription drugs – particularly opioid pain relievers – have increased dramatically, nearly doubling between 2000 and 2014. New Mexico's death rate from drug overdose grew in lockstep with the increasing sale and distribution of opioid drugs by the manufacturers and wholesale distributors. The New Mexico Department of Health estimates that in 2007 alone prescription opioid abuse and misuse cost the State of New Mexico \$890 million for items such as excess medical and prescription costs, lost earnings from premature deaths and costs associated with correctional facilities and police services.

Attorney General Balderas filed this lawsuit as part of the Office of the Attorney General's Project OPEN: Opioid Prevention & Education Network. Through this targeted enforcement effort, the Office of the Attorney General works aggressively to bring civil enforcement actions against individuals and businesses who have harmed vulnerable New Mexican populations and New Mexican taxpayers.

THE PROBLEM:

- Since 2008, New Mexico has had one of the highest rates of drug overdose death in the United States.
- On average, over 500 New Mexicans die annually of a drug overdose, and approximately 70% of those deaths resulted from either opioid pain relievers or heroin.
- On average, that's seven deaths a week resulting from either opioid pain relievers or heroin.
- In Rio Arriba County and Mora County, overdose death rates were more than five times the national rate.
- DOH reports that Naloxone was deployed by self-reporting individuals pursuant to the needle exchange program 850 times in 2014 and 790 times in 2015 in the State of New Mexico (otherwise resulting in overdose/wrongful deaths in the State of New Mexico).
- Close to half of NM counties have a drug overdose death rate that is one and half times higher than the US rate.
- New Mexico's death rate from prescription drugs exceeds the statewide death rate from illicit drugs in more than half of the counties.
- Over the last 14 years, we have seen overdose deaths caused by prescription opioids rise faster than deaths caused by heroin.
- Drug overdose deaths and opioid-involved deaths continue to increase in the United States. The majority of drug overdose deaths (more than six out of ten) involve an opioid. Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled.
- From 2000 to 2015 more than half a million people died in the US from drug overdoses.
- In New Mexico, Hispanic men had the highest drug overdose death rate with an average age of death of 45.
- In Lincoln County, 92.6% of every 100 citizens has a prescription for opioids.
- In over a third of NM counties, over 80% of every 100 citizens has a prescription for opioids.
- Approximately 175,800 people in New Mexico are currently prescribed opioids.
- More people use prescription opioids than tobacco.
- In Rio Arriba County, 64 out of every 1000 babies born suffers from Neonatal Abstinence Syndrome--a condition caused when the child is exposed to addictive opioids while in the womb and is born addicted. That's 10 times the national average for this syndrome.
- Drug overdose deaths as a leading cause of death has surpassed motor vehicle crash deaths in New Mexico.

Please see attached for a copy of the complaint.

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

**PLAINTIFF’S COMPLAINT FOR DAMAGES,
RESTITUTION, AND CIVIL PENALTIES**

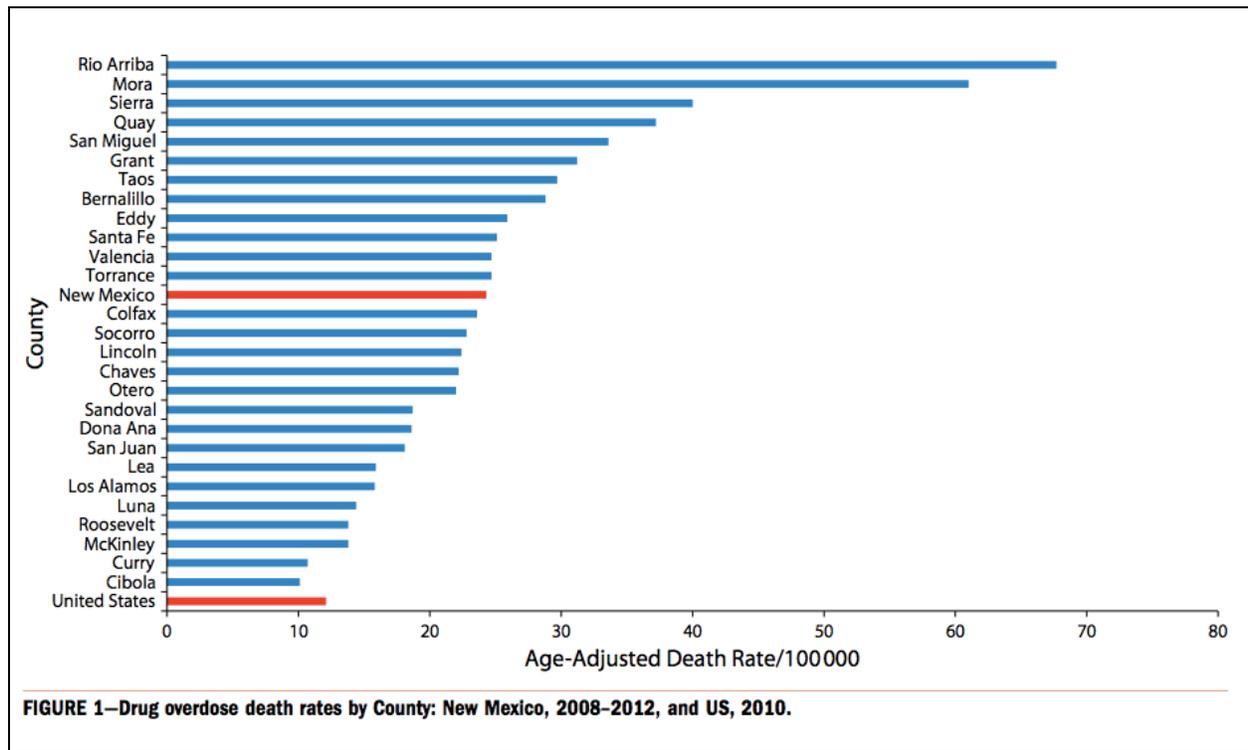
Plaintiff, the State of New Mexico, by Hector Balderas, Attorney General (the “State”), brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; 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. Since 2008, New Mexico has had one of the highest rates of drug overdose death in the United States. Between 2008-2012, 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:²



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 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 et al., *Geographic Variation in Opioid Prescribing in the U.S.*, 13 J. Pain 988 (2012).

4. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”³

5. **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 ASA®), ibuprofen (Vicoprofen®) and antihistamines (Hycomine®). Most often these drugs are abused by oral rather than intravenous administration.⁴

6. **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.⁵

³ See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

⁴ See Drug Enf't Admin., *Drug Fact Sheet: Hydrocodone* (n.d.), https://www.dea.gov/druginfo/drug_data_sheets/Hydrocodone.pdf.

⁵ See Drug Enf't Admin., *Drug Fact Sheet: Oxycodone* (n.d.), https://www.dea.gov/druginfo/drug_data_sheets/Oxycodone.pdf.

7. 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.

8. The State also brings this suit against the wholesale distributors of these highly addictive drugs, which breached 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.

9. 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, and 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.

10. The State brings this action exclusively under the law 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.

11. 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

12. 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); 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 NMSA 1978, Sections 30-8-1, 30-8-8 (1963).

B. Defendants

13. 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.

14. 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.

15. 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

16. 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.

17. 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").

18. 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.

19. 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.

20. 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.”⁶ 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.”⁷ 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.⁸

21. 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

⁶ *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s0301bl.pdf.

⁷ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s0151bl.pdf.

⁸ 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>.

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.

22. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.⁹ 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®.¹⁰ 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.”

23. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of

⁹ *E.g.*, ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last visited Aug. 21, 2017).

¹⁰ Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

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

24. 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.

25. 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."

26. 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.

27. 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.”

28. 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.

2. Distributor Defendants

29. 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.

30. 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.

31. 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.”

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

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

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

35. 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.

36. 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.

37. 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.

38. 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.

39. 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

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

41. 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).

42. 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.

43. 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 sanctionable.

44. 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

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

¹¹ *See* Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

46. 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.¹²

47. 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 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.

¹² Katherine M. Keyes et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

- Almost 5,500 people start to misuse prescription painkillers every day.¹³

48. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.¹⁴

49. 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.¹⁵

50. 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.¹⁶

51. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.¹⁷

52. 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***

¹³ 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.

¹⁴ See Califf et al., *supra* note 3.

¹⁵ See *id.*

¹⁶ 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).

¹⁷ See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

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.¹⁸

53. The societal costs of prescription drug abuse are “huge.”¹⁹

54. 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.²⁰

55. 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.²¹

56. In 2016, the President of the United States declared an opioid and heroin epidemic.²²

57. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.²³

¹⁸ See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 *Morbidity & Mortality Wkly. Rep.* 1378 (2016).

¹⁹ 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].

²⁰ 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).

²¹ See Volkow & McLellan, *supra* note 1.

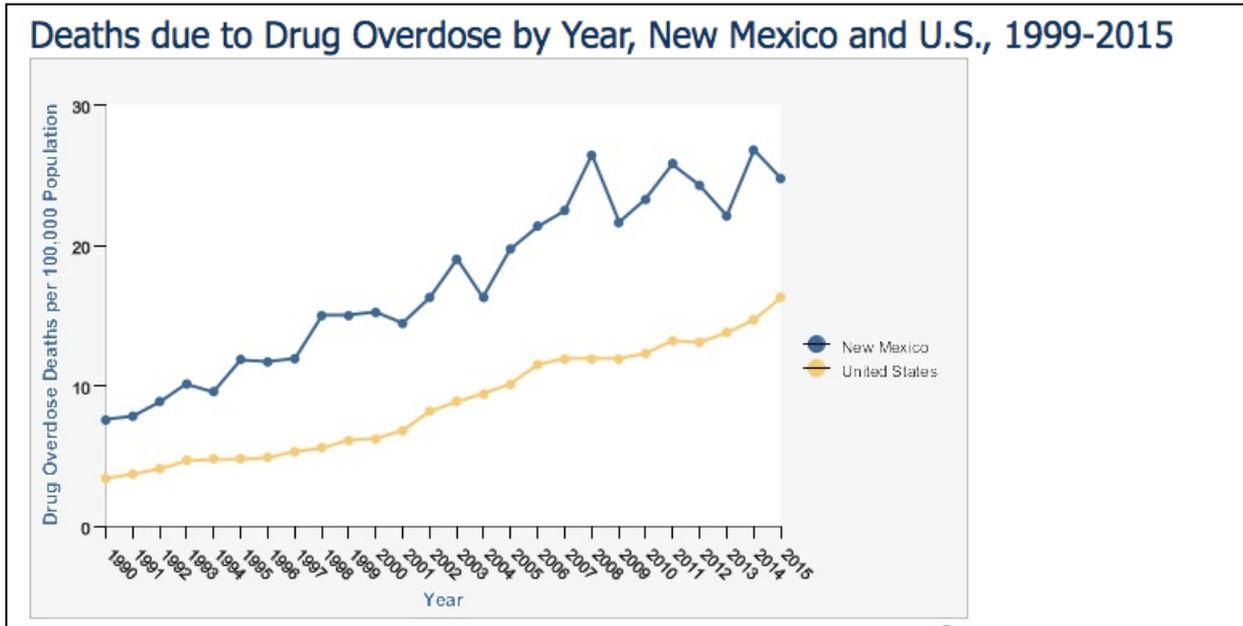
²² See Proclamation No. 9499, 81 *Fed. Reg.* 65,173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”).

²³ 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>.

B. NEW MEXICO'S OPIOID EPIDEMIC

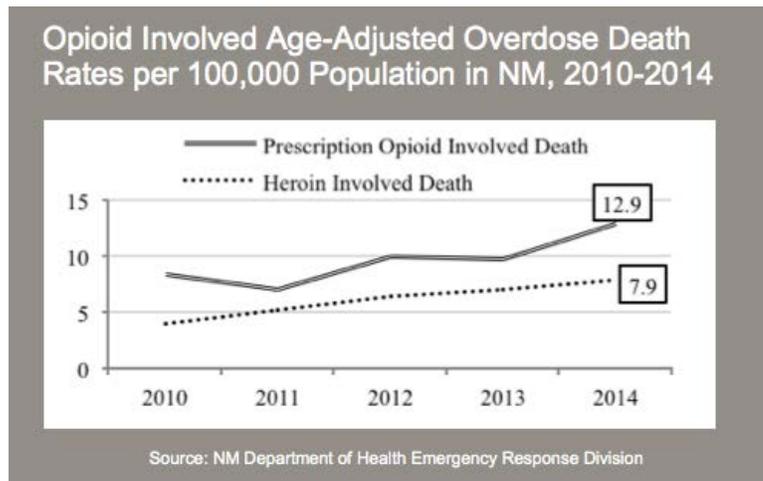
58. New Mexico has been especially ravaged by the national opioid crisis.

59. 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:



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>.

60. 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

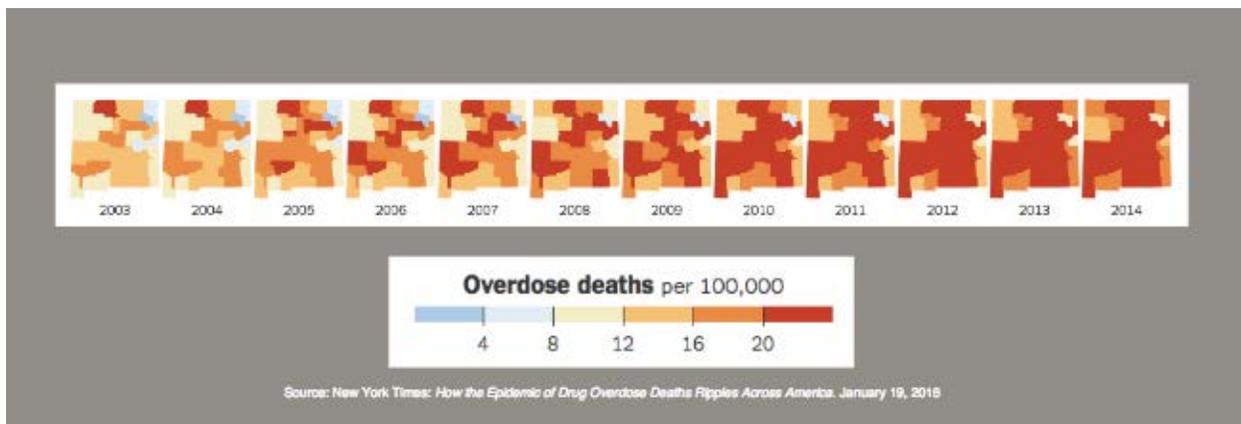


overdose deaths in New Mexico involving opioid pain relievers or heroin nearly doubled between

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%.

61. 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.

62. 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>.

63. 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 25.²⁴

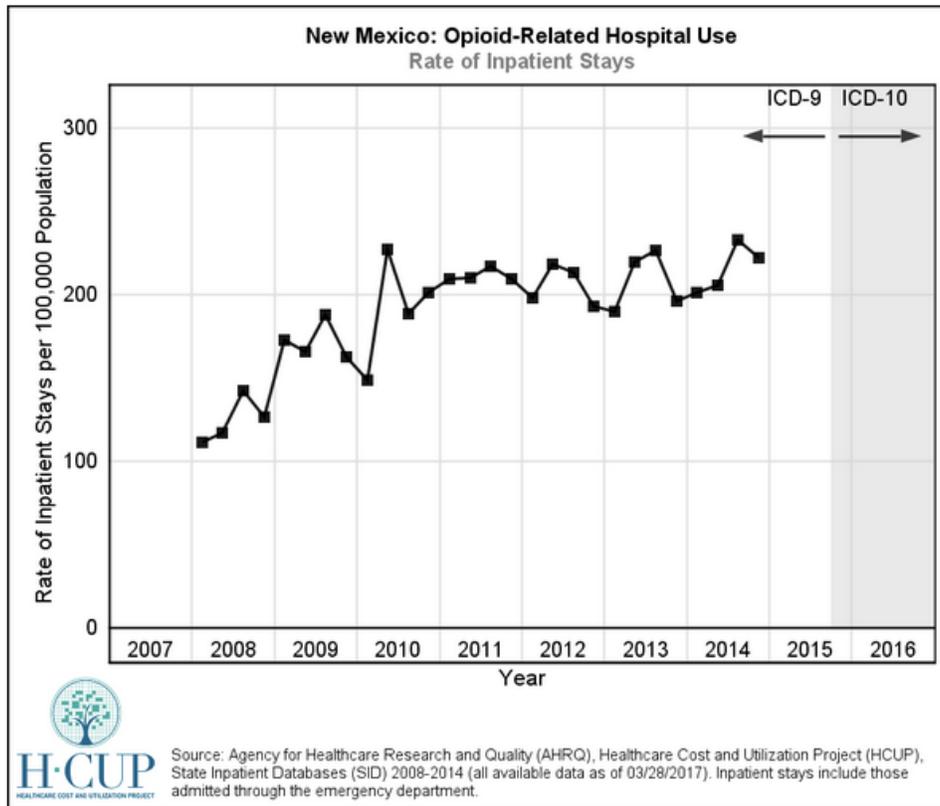
64. From 2000 through 2017, the New Mexico Medicaid Program spent at least \$72.8 million for opioid pain medications.²⁵

65. 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.

66. 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:

²⁴ 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.

²⁵ 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.



67. Between 2010 and 2015, the rate of opioid-overdose-related emergency department visits in New Mexico increased by almost 10%.²⁶

68. 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.²⁷ 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 2011.²⁸

²⁶ New Mexico Dep’t of Health, *New Mexico Substance Abuse Epidemiology Profile Report: Health Indicator Report of Drug Overdose Deaths* (2017) at 37.

²⁷ 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.

²⁸ 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*

69. 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.²⁹

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

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

71. 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.

72. 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 spend,

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

²⁹ 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.

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.

73. 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.

74. 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.

75. 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 2009.³⁰ In an

³⁰ 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,

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.”³¹ 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

76. 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.

77. 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>.

³¹ Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), <http://turnthetidex.org/>.

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

78. 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

79. 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.

80. 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.

81. 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.

82. 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.

83. 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.”³²

b) Indirect Marketing

84. 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”).

85. 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.

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

³² 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>.

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.

87. 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.

88. 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.

89. 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.³³ By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions.

90. 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.”

91. 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 Treatment of

³³ 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.

Pain.”³⁴ 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.

92. 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.

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

94. 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, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) / American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was

³⁴ 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/>.

also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by the Manufacturer Defendants.

95. 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.”³⁵

96. 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.”³⁶ Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”³⁷

³⁵ Good Morning America (ABC television broadcast Aug. 30, 2010).

³⁶ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

³⁷ *Id.*

97. 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).

98. 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.

99. 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.”³⁸

³⁸ 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/>.

100. 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.³⁹

101. 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.”⁴⁰ 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.”⁴¹

102. 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

³⁹ 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).

⁴⁰ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

⁴¹ 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.

103. 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.

104. 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”).⁴²

105. 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,

⁴² 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.

106. 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.

107. 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."

108. 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.

109. 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."⁴³

110. 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.

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

⁴³ 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.

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

112. 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.

113. 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.

114. 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.⁴⁴

115. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”) and continued to recommend the use of opioids to treat chronic pain.⁴⁵ 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.

116. 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.⁴⁶ One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These

⁴⁴ *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).

⁴⁵ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 *J. Pain* 113 (2009).

⁴⁶ *Id.*

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.

117. 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.

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

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

119. 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.

120. 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.⁴⁷

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

⁴⁷ 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>.

- 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.”⁴⁸
- h. Upon information and belief, consistent with the Manufacturer Defendants’ published marketing materials, detailers for Purdue, Endo, Janssen, and Cephalon 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.
- i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “patients rarely become addicted to prescribed opioids,” citing research by their KOL, Dr. Portenoy.⁴⁹

121. 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

⁴⁸ 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>.

⁴⁹ 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.

“[e]xtensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .).”⁵⁰ . The 2016 CDC Guideline further explains that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”⁵¹.

122. 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.⁵²

123. 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,

⁵⁰ 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>.

⁵¹ *Id.* at 2, 25.

⁵² 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>.

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.”⁵³ Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however, to make those statements in New Mexico.

124. 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.

125. 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

⁵³ 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.

hoarding, are all signs of pseudoaddiction, rather than true addiction.⁵⁴ The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.⁵⁵

- 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 he is

⁵⁴ Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.

⁵⁵ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

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.

126. 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.

127. 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.

128. 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.”⁵⁶

129. 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.⁵⁷

⁵⁶ *Id.* at 11.

⁵⁷ *Id.* at 26.

130. 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.⁵⁸

131. 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

⁵⁸ APF, *Policymaker's Guide*, *supra* note 48, at 32.

have “no ceiling dose” and insinuated that they are therefore the most appropriate treatment for severe pain.⁵⁹ This publication is still available online.

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain.”
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased. . . . You won’t ‘run out’ of pain relief.”⁶⁰
- 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

⁵⁹ APF, *Treatment Options*, *supra* note 47, at 12.

⁶⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

that “the need for higher doses of medication is not necessarily indicative of addiction,” but inaccurately downplayed the risks from high opioid dosages.⁶¹

- h. In 2007, Purdue sponsored a CME entitled “Overview of Management Options” that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, “the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose.⁶²
- 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.⁶³

132. 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.”⁶⁴ More specifically, the CDC explains that “there is now an established body of scientific evidence

⁶¹ APF, *Policymaker’s Guide*, *supra* note 48, at 32.

⁶² The College on Problems of Drug Dependence, *About the College*, <http://cpdd.org> (last visited Aug. 21, 2017).

⁶³ Brief of APF, *supra* note 49, at 9.

⁶⁴ 2016 CDC Guideline, *supra* note 50, at 22–23.

showing that overdose risk is increased at higher opioid dosages.”⁶⁵The CDC also states that there is an increased risk “for opioid use disorder, respiratory depression, and death at higher dosages.”⁶⁶ That is why the CDC advises doctors to “avoid increasing dosage” to above 90 morphine milligram equivalents per day.⁶⁷

133. 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.

134. 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.”⁶⁸ Also troubling, Opana ER can be prepared for snorting using commonly available methods and “readily prepared for injection.”⁶⁹ The letter discussed “the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection.”⁷⁰ Endo’s own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

⁶⁵ *Id.* at 23–24.

⁶⁶ *Id.* at 21.

⁶⁷ *Id.* at 16.

⁶⁸ 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.

⁶⁹ *Id.* at 6.

⁷⁰ *Id.* at 6 n.21.

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

135. 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 \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.⁷¹ 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.

136. 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.
- 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

⁷¹ *Id.* at 15.

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."⁷² 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, 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

⁷² APF, *Treatment Options*, *supra* note 47.

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."⁷³ 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."⁷⁴ 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.

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

⁷³ E.g., NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

⁷⁴ APF, *Policymaker's Guide*, *supra* note 48, at 29.

138. 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.”⁷⁵ And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

139. 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.⁷⁶ 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

⁷⁵ Letter from Thomas Abrams to Doug Boothe, *supra* note 32.

⁷⁶ 2016 CDC Guideline, *supra* note 50, at 12.

under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of 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.

140. 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.

141. 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.⁷⁷

142. 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.⁷⁸ 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.”⁷⁹

143. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to

⁷⁷ 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).

⁷⁸ 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>.

⁷⁹ *Id.*

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.

144. 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.

145. 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.⁸⁰

146. 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.

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

147. 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

⁸⁰ 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/>.

benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

148. 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.⁸¹ The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. *Id.* at 27. 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.

4. The Manufacturing Defendants Fraudulently Concealed Their Misconduct.

149. 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

⁸¹ 2016 CDC Guideline, *supra* note 50, at 13.

addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

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

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

did not support. The Manufacturer Defendants invented “pseudoaddiction” and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales. The lack of support for the Manufacturer Defendants’ deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the 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.

152. The New Mexico Board of Pharmacy governs for 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.

153. 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 statutes, 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).

154. 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.”).

155. 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).⁸² It is a crime to intentionally fail to furnish

⁸² 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.

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).

156. 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.

157. 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).

158. 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.

159. 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.”⁸³

⁸³ *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.

160. 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.

21 C.F.R. § 1301.74(b).⁸⁴ 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.

161. “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

⁸⁴ 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.

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.

162. 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.⁸⁵

163. The Defendant Wholesale Distributors have admitted that they are responsible for reporting suspicious orders.⁸⁶

164. 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

⁸⁵ 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).

⁸⁶ *See* Brief for HDMA and NACDS, *supra* note 85, 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).”).

into other than legitimate medical, scientific, and industrial channels.”⁸⁷ The letter also instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”⁸⁸ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”⁸⁹

165. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.⁹⁰ 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.”⁹¹ 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 particular

⁸⁷ Rannazzisi Letter, *supra* note 83, at 2.

⁸⁸ *Id.* at 1.

⁸⁹ *Id.* at 2.

⁹⁰ 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.

⁹¹ *Id.*

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.⁹²

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."⁹³

⁹² *Id.*

⁹³ *Id.*

166. 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.”⁹⁴

167. 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.⁹⁵

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

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

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

⁹⁴ See Brief of HDMA, *supra* note 19, 2012 WL 1637016, at *2.

⁹⁵ 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).

171. Each Defendant owes a duty under New Mexico law to report suspicious orders of prescription opioids.

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

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

174. 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.

175. 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.⁹⁶

176. 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 red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.⁹⁷

⁹⁶ 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.

⁹⁷ *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)).

177. 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.

178. 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.

179. 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.

180. 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.

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

182. 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 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.

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

184. 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.⁹⁸

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

186. 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.

187. 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 (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”⁹⁹

■ 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

⁹⁸ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

⁹⁹ Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4–5.

policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”¹⁰⁰

■ 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.”¹⁰¹

■ 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.”¹⁰²

■ 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.”¹⁰³

■ 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.”¹⁰⁴

188. 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.¹⁰⁵

189. 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

¹⁰⁰ *Id.* at *8 (citations and quotation marks omitted).

¹⁰¹ *Id.* at *14.

¹⁰² *Id.* at *22.

¹⁰³ *Id.* at *24–25.

¹⁰⁴ *Id.* at 26.

¹⁰⁵ See Brief of HDMA, *supra* note 19, 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”).

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.

190. 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 certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”¹⁰⁶ 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.

¹⁰⁶ 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>.

§ 1306.04(a).”¹⁰⁷ 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 CSA 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.”¹⁰⁸ 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.¹⁰⁹

191. 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.¹¹⁰ In the 2008 Settlement Agreement, McKesson “recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA,” but had failed to do so.¹¹¹ 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.”¹¹² As a result of these violations, McKesson was fined and required to pay to the United States \$150,000,000.¹¹³

¹⁰⁷ *Id.* at 4.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at 6.

¹¹⁰ *Id.* at 4.

¹¹¹ *Id.*

¹¹² *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>.

¹¹³ *See* 2017 Settlement Agreement and Release, *supra* note 112, at 6.

192. 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 2012.¹¹⁴ 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.¹¹⁵ 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, 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;

¹¹⁴ 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>.

¹¹⁵ *Id.*

(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.

193. 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.¹¹⁶

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

195. 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.

196. 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.

197. 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

¹¹⁶ 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->.

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.

198. 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.”¹¹⁷ 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.

199. 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.”¹¹⁸ Again, given McKesson’s historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

200. 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

¹¹⁷ 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.

¹¹⁸ 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.

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.

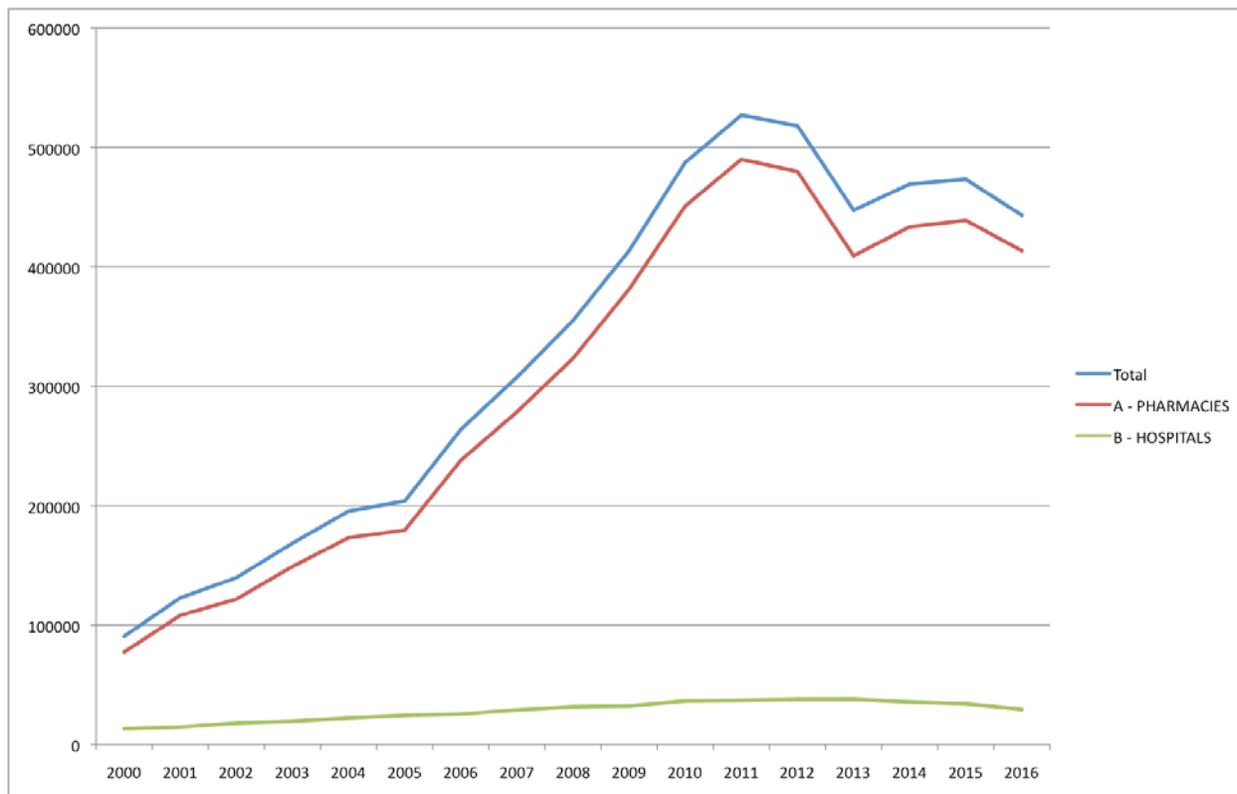
201. By misleading the public and the State of New Mexico about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the State now asserts. The State did not know of the existence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

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

202. As the Manufacturing 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.

203. 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.

204. 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.

205. 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.”¹¹⁹

¹¹⁹ See Dart at al., *supra* note 11.

206. 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.¹²⁰

207. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”¹²¹

208. 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.¹²²

209. As discussed above in paragraphs 57 through 66, 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.

210. 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.

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

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

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

¹²⁰ See Volkow & McLellan, *supra* note 1.

¹²¹ See Califf et al., *supra* note 3.

¹²² See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., *supra* note 13.

214. 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.

215. 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.”¹²³

216. 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.¹²⁴

217. These community-based problems require community-based solutions that have been limited by “budgetary constraints at the state and Federal levels.”¹²⁵

218. 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.

F. TOLLING OF THE STATUTE OF LIMITATIONS

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

¹²³ See Rudd et al., *supra* note 20, at 1145.

¹²⁴ 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.

¹²⁵ 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.

1. Continuing Conduct

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

221. 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

222. 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 goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State of New Mexico, that they are working to curb the opioid epidemic.

223. 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.”¹²⁶

¹²⁶ Bernstein et al., *supra* note 117.

224. 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.”¹²⁷

225. 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:¹²⁸

- “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.”
- “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.”

¹²⁷ Higham et al., *supra* note 118.

¹²⁸ Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *3-4, *25.

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.

226. 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.

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

3. Fraudulent Concealment.

228. 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, and 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.

229. 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.

230. 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

231. 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)

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

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

234. 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.

235. 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.

236. 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.

237. 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.

238. 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.

239. 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, § 30-8-8-1.

240. 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.

241. 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.

242. 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.

243. 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.”).

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

245. 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.

246. 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.

247. 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.

248. Plaintiff, the State of 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)
Against All Defendants Except Purdue

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

250. 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.

251. 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).

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

253. 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.

254. 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).

255. 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.

256. 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 id.* §§ 57-12-2(D)(2) (causing confusion or misunderstanding as to approval or certification of goods or services), 57-12-2(D)(15) (stating that a transaction involves rights it does not involve).

257. 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.

258. As alleged herein, each Manufacturer Defendant (except Purdue), 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).

259. 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 NMSA 1978, § 57-12-2(D)(7).

260. 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).

261. 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).

262. 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 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.

263. 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.

264. Notwithstanding any other language in this Complaint, the State does not at this time bring an Unfair Practices Act Count against PURDUE PHARMA L.P., PURDUE PHARMA INC., or THE PURDUE FREDERICK COMPANY.

265. 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.

266. 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.

267. 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.

268. 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.

269. 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 Board of Pharmacy, and New Mexico consumers, who paid for prescription opioids for chronic pain.

270. 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.

271. 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.

272. 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.

273. 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.

274. 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.

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

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

277. 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, brochures, packaging constitutes a separate violation pursuant to the Unfair Trade Practices Act.

278. 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)

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

280. 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.

281. 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.

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

283. 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.

284. 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.

285. 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.

286. 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.

287. 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 actively harmed by Defendants’ actions.

288. 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.

289. 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.

290. 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.

291. 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.

292. 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.

293. 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 Manufacturer Defendants Purdue, Janssen, Cephalon, and Endo)

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

295. 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, Sections 30-42-1 to -6, against Defendants Purdue, Janssen, Cephalon and Endo. The Attorney General has the specific statutory authority to bring this action pursuant to NMSA 1978, Sections 30-42-5, 30-42-6. Defendants are persons subject to the Racketeering Act. NMSA 1978, § 30-42-3(B).

A. The Opioids Marketing Enterprise.

296. Defendants formed an association-in-fact enterprise (occ. “Opioids Marketing Enterprise”), and participated in the affairs of this enterprise when distributing highly dangerous, addictive opioid drugs in New Mexico. The Opioids Marketing Enterprise consists of (a) Defendants, including their employees and agents; and (b) the Front Groups, including their employees and agents; and (c) the KOLs.

297. Defendants, the Front Groups, and the KOLs participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of profiting from the sale of opioids, through a pattern of racketeering activity.

298. Defendants conducted the Opioids Marketing Enterprise, and participated in the enterprise, by engaging in a pattern of racketeering activity.

299. Defendants received proceeds derived from a pattern of racketeering activity in which Defendants participated, and used or invested at least a part of the proceeds or the proceeds

derived from the investment or use, in the acquisition of an interest in, or the establishment or operation of, the Opioids Marketing Enterprise.

300. Defendants engaged in a pattern of racketeering activity to acquire or maintain an interest in or control of the Opioids Marketing Enterprise.

301. The Opioids Marketing Enterprise is an ongoing and continuing business organization that created and maintained systemic links for a common purpose: to ensure the prescription of opioids for chronic pain.

302. To accomplish this purpose, the Opioids Marketing Enterprise periodically and systematically misrepresented – either affirmatively or through half-truths and omissions – to the general public, the State, and New Mexico consumers, the risks and benefits of using opioids for chronic pain. The Opioids Marketing Enterprise concealed from the public, the State, and New Mexico consumers, the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioids Marketing Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

303. The persons engaged in the Opioids Marketing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants, Front Groups and KOLs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants, Front Groups and KOLs share information regarding overcoming objections to the use of opioids for chronic pain. Defendants, the Front Groups and KOLs functioned as a continuing unit for the purposes of

implementing the Opioids Marketing Scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

304. At all relevant times, KOLs were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers and the State. But for the Opioids Marketing Enterprise's unlawful fraud, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Opioids Marketing Enterprise's scheme, and reaped substantial benefits.

305. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities in New Mexico and throughout the United States, the Front Groups and KOLs did not challenge Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioids Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

306. The Front Groups and KOLs participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity including multiple instances of fraud, they knowingly made material misstatements or omissions to New Mexico physicians, consumers, the State and the general public in furtherance of the fraudulent scheme, including that:

- a. it was rare, or there was a low risk, that Defendants’ opioids could lead to addiction;¹²⁹
- b. the signs of addiction were actually signs of undertreated pain that should be treated by more opioids;¹³⁰
- c. opioid dependence could be easily addressed by tapering and that opioid withdrawal is not difficult;¹³¹
- d. doctors could increase opioid dosages indefinitely without added risk;¹³²
- e. long-term opioid use improved patients’ function and quality of life;¹³³ and
- f. Purdue’s OxyContin provided 12 hours of continuous pain relief.¹³⁴

307. Defendants alone could not have accomplished the purpose of the Opioids Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as “neutral” and more “scientific” than Defendants themselves. Without these misrepresentations, the Opioids Marketing Enterprise could not have achieved its common purpose.

308. The impacts of the Opioids Marketing Enterprise’s scheme are still in place – i.e., the opioids continue to be prescribed and used for chronic pain throughout the State of New Mexico, and the epidemic continues to consume the resources of New Mexico’s health care and law enforcement systems.

¹²⁹ APF, *Treatment Options*, *supra* note 47 (sponsored by Cephalon and Purdue); APF, *Policymaker’s Guide*, *supra* note 48 (sponsored by Purdue).

¹³⁰ *See, e.g.*, Mark S. Wallace, M.D., Dir., Ctr. For Pain Medicine, Univ. of Cal. San Diego, Nat’l Initiative on Pain Control, *Opioid Analgesic Slide Module* (n.d.) (sponsored by Endo), http://www.acmt.net/Library/2012_Prescription_Opioid_Syllabus/1_4_3BW_Wallace_ppt.pdf.

¹³¹ APF, *Policymaker’s Guide*, *supra* note 48 (sponsored by Purdue).

¹³² *Id.*; APF, *Treatment Options*, *supra* note 47 (sponsored by Cephalon and Purdue); McCaffery & Pasero, *supra* note 60 (editor is a key opinion leader for Endo Pharmaceuticals).

¹³³ Fishman, *supra* note 54 ((sponsored by Endo, Cephalon, and Purdue); APF, *Treatment Options*, *supra* note 47 (sponsored by Cephalon and Purdue); NIPC, *supra* note 73.

¹³⁴ Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain (May 31, 1996) (“OxyContin Tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night.”), <http://documents.latimes.com/oxycontin-press-release-1996/>.

309. The foregoing evidences that Defendants, the Front Groups and the KOLs were each willing participants in the Opioids Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

B. Conduct of the Opioids Marketing Enterprise

310. During the time period described in this Complaint, from approximately 2006 to the present, Defendants exerted control over the Opioids Marketing Enterprise and participated in the operation and management of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

- a. Defendants created a body of deceptive and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;
- b. Defendants selected, cultivated, promoted and paid the KOLs based solely on their willingness to communicate and distribute Defendants' messages about the use of opioids for chronic pain;
- c. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- d. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;
- e. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- f. Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- g. Defendants developed and disseminated pro-opioid treatment guidelines;
- h. Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by Defendants, such as veterans and the elderly, and then funded that distribution;

- i. Defendants concealed their relationship to and control of Front Groups and KOLs from the State and the public at large; and
- j. Defendants intended that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

311. The scheme had a hierarchical decision-making structure that was headed by Defendants. Defendants controlled representations made about their drugs, and doled out funds to Front Groups and payments to KOLs to ensure that their representations were consistent with Defendants' messaging nationwide and throughout the State of New Mexico. Front Groups were dependent on Defendants for their financial support, and KOLs were professionally dependent on Defendants for the development and promotion of their careers.

312. The Front Groups also participated in the conduct of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

- a. The Front Groups promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages;
- b. The Front Groups distribute promotional and other materials claiming that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and
- c. The Front Groups concealed their connections to Defendants.

313. The KOLs also participated in the conduct of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

- a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages;
- b. The KOLs distributed promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and
- c. The KOLs concealed their connections to and sponsorship by Defendants.

314. The scheme devised and implemented by Defendants, as well as other members of the Opioids Marketing Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure payment for prescriptions of Defendants' opioids by New Mexico patients and the State, including the New Mexico Human Services Department, Medical Assistance Division. The Scheme was a continuing course of conduct, and many aspects of it continue through to the present.

C. Pattern of Racketeering Activity

315. Defendants conducted and participated in the conduct of the affairs of the Opioids Marketing Enterprise through a pattern of racketeering as defined in NMSA 1978, Section 30-42-3. Defendants' conduct as described above constitutes fraud chargeable or indictable under the laws of New Mexico and punishable by imprisonment for more than one year, which is defined as racketeering. NMSA 1978, § 30-42-3(A)(6).

316. "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. Here, Defendants intended to and did by means of fraudulent misrepresentations regarding the benefits of opioid prescriptions for treating chronic pain, succeed in misappropriating State funds, 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, § 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, § 10-7C-8 (1990); and,
- 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, §§ 22-29-1 to -12 (2003, as amended through 2011).

317. Defendants made the misrepresentations regarding the opioids' benefits with actual fraudulent intent to deceive prescribers in New Mexico, New Mexico government payor programs (*inter alia* Medicaid), and New Mexico patients. Defendants' deception was massively successful.

318. 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). The Manufacturer Defendants did not 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), 30-31-25(A)(4). Among other infractions, Defendants did not comply with 21 U.S.C. § 823 and its attendant regulations (*e.g.*, 21 C.F.R. § 1301.74),¹³⁵ which are incorporated into New Mexico state law, or the New Mexico Pharmacy Board regulations. The Defendants failed to furnish notifications required under the Substances Control Act. NMSA 1978, § 30-31-24(A)(3). Relatedly, the Defendants omitted required reports. NMSA 1978, § 30-31-25(A)(4). Trafficking in controlled substances in violation of Section 30-31-20 is defined as "racketeering." § 30-42-3(A)(13). Distribution of controlled substances in violation of Sections 30-31-21 and 30-31-22 is defined as "racketeering." § 30-42-3(A)(19).

¹³⁵ 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.

319. The pattern of racketeering activity alleged herein and the Opioids Marketing Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the Opioids Marketing Enterprise.

320. 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.

321. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants', the Front Groups' and the KOLs' books and records. Indeed, an essential part of the successful operation of the Opioids Marketing Enterprise alleged herein depended upon secrecy.

322. 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 the New Mexico consumers and the State. Defendants, the Front Groups and the KOLs calculated and intentionally crafted the opioids marketing scheme to increase and maintain their increased profits, without regard to the effect such behavior had on New Mexico consumers and the State. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding Defendants' products.

323. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, and then subsequently failing to disclose such practices to New Mexico consumers or the State, Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

324. It was foreseeable to Defendants that the Front Groups and the KOLs would distribute publications and otherwise misrepresent that the benefits of using opioids for chronic pain outweighed the risks of doing so.

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

D. Damages

326. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused the State, as well as consumers within New Mexico, to be injured in their business or property because they paid for opioid prescription for chronic pain for which they would not otherwise have paid.

327. The State's injuries, and those of New Mexico consumers, were proximately caused by Defendants' racketeering activities. But for the misstatements made by Defendants, the Front Groups and the KOLs and the scheme employed by the Opioids Marketing Enterprise, the State and New Mexico consumers would not have paid for opioid prescriptions for chronic pain.

328. The State's injuries were directly caused by Defendants' racketeering activities. Although the misstatements made by the Front Groups and the KOLs in furtherance of the Opioids Marketing Enterprise were directed primarily to health care providers, those providers did not have to make payments for opioids prescribed for chronic pain. Therefore, New Mexico health care providers did not suffer the same injuries alleged in this Complaint.

329. The State and its citizens were most directly harmed, and there is no other Plaintiff better situated to seek a remedy for the economic harms at issue here.

330. Plaintiff, 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 fees and all costs and expenses of suit (N.M. Rev. Stat. § 30-42-6), and pre- and post-judgment interest.

**COUNT V
RACKETEERING ACT
NMSA 1978, §§ 30-42-1 to -6.
(Against Distributor Defendants Cardinal Health, Inc., McKesson Corporation, and
AmerisourceBergen Drug Corporation)**

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

332. 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, Sections 30-42-1 to -6, against Defendants Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation. The Attorney General has the specific statutory authority to bring this action pursuant to Sections 30-42-5, 30-42-6. Defendants are persons subject to the Racketeering Act. § 30-42-3(B).

A. The Opioids Diversion Enterprise.

333. Defendants formed an association-in-fact enterprise (occ. “Opioids Diversion Enterprise”), and participated in the affairs of this enterprise when distributing highly dangerous, addictive opioid drugs in New Mexico. The Opioids Diversion Enterprise consist of (a) Defendants, including their employees and agents; and (b) each Defendants’ retail pharmacies¹³⁶ which placed orders for vast quantities of opioids. Indeed, the Defendants could not have diverted opioids without the participation of retail pharmacies. The events described herein required retail pharmacies to place orders for these vast quantities of opioids.

¹³⁶ As used in Count V herein, the words “pharmacies” and “pharmacy” exclude any pharmacy owned or directly controlled by the State.

334. The Defendants and their pharmacy customers participated in the conduct of the Opioids Diversion Enterprise, sharing the common purpose of profiting from the sale of opioids, through a pattern of racketeering activity, which includes multiple violations of New Mexico state criminal law.

335. Defendants conducted the Opioids Diversion Enterprise, and participated in the enterprise, by engaging in a pattern of racketeering activity.

336. Defendants received proceeds derived from a pattern of racketeering activity in which Defendants participated, and used or invested at least a part of the proceeds or the proceeds derived from the investment or use, in the acquisition of an interest in, or the establishment or operation of, the Opioid Diversion Enterprise.

337. Defendants engaged in a pattern of racketeering activity to acquire or maintain an interest in or control of the Opioids Diversion Enterprise.

338. The Opioids Diversion Enterprise is an ongoing and continuing business organization that created and maintained systemic links for a common purpose: to profit from the sale of opioid prescription pills. Defendants conducted this enterprise notwithstanding that their failure to abide by mandatory controls constituted unlawful diversion of a dangerous controlled substance.

339. The system is structured such that wholesalers and pharmacies see greater profits at higher volumes. As a result, Distributor Defendants are financially discouraged from undertaking efforts to combat opioid abuse. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost (“WAC”). Discounts and rebates may be offered by the manufacturers based on, *inter alia*, market share and volume. Thus, the Distributor Defendants are incentivized to order greater amounts so that they

can decrease the cost per pill. The Distributor Defendants used the decreased cost per pill to increase their market share (and thus, profits), by offering more competitive prices, or they maintained their prices and pocketed the difference as additional profit. Either way, increased sales volumes result in increased profits. At every turn, each Defendant maximized its profits through discounts and rebates by ordering and selling more opioids.¹³⁷

340. As described above and expressly incorporated herein, the Distributor Defendants: A) were placed on notice by the DEA, and were the subject of repeated DEA enforcement actions; and B) misrepresented their compliance with their legal obligations to maintain a closed system.

341. The Opioid Diversion Enterprise has caused opioids to be abused throughout New Mexico, with an ongoing cascade of human suffering and death that continues to consume the resources of the State's health and human services, health care, and law enforcement systems.

342. Defendants and their retail pharmacy customers were each willing participants in the Opioids Diversion Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

B. Conduct of the Opioids Diversion Enterprise

343. To accomplish the common purpose of profiting from the sale of opioid prescription pills, the Opioids Diversion Enterprise periodically and systematically misrepresented – either affirmatively or through half-truths and omissions – to the general public, the State, New Mexico consumers, and the New Mexico Board of Pharmacy, that the Distributor Defendants were fulfilling the requirements of their New Mexico wholesale distributor licenses when, in fact, the

¹³⁷ The Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, (2005),

<https://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>.

duty to abate diversion for non-medical purposes was being ignored in pursuit of ever increasing profits.

344. The persons engaged in the Opioids Diversion Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities.

345. The Opioids Diversion Enterprise functions as a continuing unit for the purposes of profiting from the sale of opioid prescription drugs. Defendants conduct, participate in, maintain an interest in, and control the Opioids Diversion Enterprise and use proceeds from the sale of opioids to further conduct the enterprise.

346. At all relevant times, the retail pharmacy customers were aware of Defendants' conduct, were a knowing and willing participant in that conduct, and reaped benefits from that conduct.

347. The sheer volume of prescription opioids flooding out of the doors of the Distributor Defendants and into communities across the country, including New Mexico, shocks the conscience and required the Distributor Defendants to take appropriate action, such as investigating and reporting the orders as suspicious. Given their place in the supply chain, the Distributor Defendants are uniquely situated to identify suspicious transactions. However, determined to increase their revenues, each of the Distributor Defendants willfully ignored obvious warning signs concerning suspicious orders. It would be virtually impossible for all of the orders to be legitimate, as there was no medical-need correlation justifying the skyrocketing orders for these addictive drugs.

348. During the time period described in this Complaint, from approximately 2006 to the present, Defendants exerted control over the Opioids Diversion Enterprise and participated in

the operation and management of the affairs of the Opioids Diversion Enterprise, directly or indirectly, in the following ways:

- a. Defendants obtained a license from the New Mexico Board of Pharmacy but, contrary to the requirements of state law, including federal laws incorporated by reference into state law, Defendants failed to take necessary action to prevent the diversion of dangerously addictive prescription opioids, and in dereliction of non-delegable duties, sold opioid pills to their retail pharmacy customers notwithstanding that the increase and quantum of addictive drug orders raised serious red flags regarding the drugs' unlawful, non-medical use;
- b. Defendants misrepresented their compliance with their legal obligations, making false assurances that their distribution complied with the law, including without limitation the requirements of a New Mexico distributor license, when, in truth, Defendants sold all the opioids they could, for profit, and in violation of their legal duties to guard against diversion of the pills for illicit purposes;
- c. Defendants refused to heed the DEA's warnings and continued to sell diverted opioids;
- d. Defendants refused to abide by the terms of DEA enforcement actions and settlements, continuing to sell diverted opioids;
- e. Defendants did not monitor, detect, investigate, refuse and report suspicious orders to the New Mexico Board of Pharmacy as required under the terms of their licenses and applicable law; and,
- f. Defendants intentionally sold the opioids unlawfully, purely for profit and without regard to the opioid plague, notwithstanding Defendants' knowledge that substantial foreseeable harm would occur.

349. The scheme devised and implemented by Defendants, as well as other members of the Opioids Diversion Enterprise, amounted to a common course of conduct intended to profit from Opioid sales.

C. Pattern of Racketeering Activity

350. Defendants conducted and participated in the conduct of the affairs of the Opioids Marketing Enterprise through a pattern of racketeering as defined in Section 30-42-3. Defendants' conduct as described above constitutes fraud, which is defined as racketeering. § 30-42-3(A)(6). Defendants' conduct as described above constitutes fraud chargeable or indictable under the laws

of New Mexico and punishable by imprisonment for more than one year, which is defined as racketeering. NMSA 1978, § 30-42-3(A)(6). “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.

351. Defendants intended to and did succeed in misappropriating State funds, as 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, § 10-7B-6;
- c. Retired public employees’ group insurance costs from the Retiree Health Care Fund, pursuant to the Retiree Health Care Act, § 10-7C-8; and,
- 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, §§ 22-29-1 to -12.

352. 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). Distributor Defendants did not 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), 30-31-25(A)(4). Among other infractions, Distributor Defendants did not comply with 21 U.S.C. § 823 and its attendant regulations (*e.g.*, 21

C.F.R. § 1301.74),¹³⁸ which are incorporated into New Mexico state law, or the New Mexico Pharmacy Board regulations. The Distributor Defendants failed to furnish notifications required under the Substances Control Act. NMSA 1978, § 30-31-24(A)(3). Relatedly, the Distributor Defendants omitted required reports. NMSA 1978, § 30-31-25)(A)(4).

353. Regardless of any licenses or registrations held by Defendants to distribute dangerous and harmful drugs, their conduct was not lawful. Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

354. The pattern of racketeering activity alleged herein and the Opioids Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the Opioids Diversion Enterprise.

355. 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.

356. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, Defendants' misrepresentations to the public, the New Mexico Board of Pharmacy, and the DEA, depended on secrecy.

357. 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 the State and its citizens. Defendants crafted the scheme to increase and maintain their increased profits, without regard to the effect such behavior

¹³⁸ 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.

had on the State and its citizens. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the distribution chain and the New Mexico Board of Pharmacy, *inter alia*, rely on the integrity of the wholesale distributors to maintain a closed system and to protect against the non-medical uses of these dangerously addictive opioid drugs.

358. Defendants have knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including the distribution of dangerous and harmful drugs to persons, in violation of the New Mexico Controlled Substances Act and distributor regulations promulgated thereto, at retail pharmacies, hospitals, and other health care facilities throughout the State of New Mexico.

359. Defendants' actions were criminal and in violation of New Mexico Statutes Chapter 30, and more specifically Section 30-31-20 to -22, which forbids the distribution of controlled substances. Defendants' conduct was not in accordance with Chapter 30, including NMSA 1978, Sections 30-31-7, 30-31-12(B), 30-31-13(A)(1), 30-31-13(C), 30-31-16(A), 30-31-20, 30-31-21, 30-31-22, 30-31-24(A), 30-31-25(A), and the mandatory control requirements incorporated by reference therein (*e.g.*, 16.19.8 NMAC, 16.19.20 NMAC). Trafficking in controlled substances in violation of Section 30-31-20 is defined as "racketeering." § 30-42-3(A)(13). Distribution of controlled substances in violation of Sections 30-31-21 and 30-31-22 is defined as "racketeering." § 30-42-3(A)(19).

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

D. Damages

361. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused the State and its citizens to be injured in their business or property because

the State has paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference.

362. The State's injuries, and those of her citizens, were proximately caused by Defendants' racketeering activities. But for 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.

363. The State's injuries, and those of her citizens, were directly caused by Defendants' racketeering activities.

364. The State was most directly harmed, and there is no other Plaintiff better situated to seek a remedy for the economic harms at issue here.

365. Plaintiff, 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 fees and all costs and expenses of suit (N.M. Rev. Stat. § 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)

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

367. 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.

368. 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 Mexico to pay for drugs that were worthless in that they had no beneficial value, and in fact, were harmful to patients.

369. 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.

370. 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, § 44-9-33A(1).

371. 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, § 44-9-33A(2).

372. By engaging in the wrongful conduct described herein, Defendants conspired to defraud the State by obtaining approval or payment on false or fraudulent claims.

373. 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.

374. 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.

375. 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.

376. 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.

377. 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)**

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

379. 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.

380. Each Defendant had an obligation to exercise reasonable care in manufacturing and distributing highly dangerous opioid drugs in the State of New Mexico.

381. Integral to duty and proximate causation is foreseeability. *Id.* at 186. 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.

382. 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.

383. 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.

384. 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.

385. 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.

386. 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.

387. 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.

388. 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.

389. 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)

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

391. 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.

392. The Distributor Defendants' violations of the law constitute negligence per se.

393. It was foreseeable that the breach of duty described herein would result in the damages sustained by the State.

394. Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent, as described above.

395. 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.

396. 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.

397. 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

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

399. 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).

400. 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 a deterrence.

401. 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 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.

Date: September 7, 2017

Respectfully Submitted,

**ATTORNEY GENERAL OF NEW MEXICO
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