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

SAMANTHA DEMARO, INDIVIDUALLY AND AS NEXT FRIEND AND GUARDIAN OF BABY J.W.L.B., ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,

Plaintiffs,

v.

CASE NO. _____

CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED

PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
MCKESSON CORPORATION;
CARDINAL HEALTH, INC.;
AMERISOURCEBERGEN CORPORATION;
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 PLC;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS LLC; and
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,
DEPOMED, INC.;
MALLINCKRODT LLC;
MALLINCKRODT PLC;
SPECGX LLC;
PAR PHARMACEUTICAL, INC.;
PAR PHARMACEUTICAL COMPANIES, INC.;
NORAMCO, INC.;
INDIVIOR, INC.;
CVS HEALTH CORPORATION;
RITE AID OF MARYLAND, INC.;
RITE AID CORP.;
WALGREENS BOOTS ALLIANCE, INC.;

WALGREEN EASTERN CO.;
WALGREEN CO.;
WAL-MART INC. f/k/a WALMART STORES, INC.;
MIAMI-LUKEN, INC.;
COSTCO WHOLESALE CORPORATION;
THE KROGER CO.;
H.D. SMITH, LLC;
H.D. SMITH HOLDINGS, LLC;
H.D. SMITH HOLDING COMPANY;
ANDA, INC.;
RICHARD S. SACKLER;
JONATHON D. SACKLER;
MORTIMER D.A. SACKLER;
KATHE A. SACKLER;
ILENE SACKLER LEFCOURT;
BEVERLY SACKLER;
THERESA SACKLER;
DAVID A. SACKLER;
RHODES TECHNOLOGIES;
RHODES TECHNOLOGIES INC.;
RHODES PHARACEUTICALS L.P.;
RHODES PHARMACEUTICALS INC.;
TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY;
THE P.F. LABORATORIES, INC.

Defendants.

CLASS ACTION COMPLAINT

NOW COME Plaintiffs and Putative Class Representative Samantha DeMaro, as the next friend and guardian of Baby J.W.L.B., individually and on behalf of all other similarly situated, hereby filing their Complaint against the Defendants for damages, equitable, statutory, and injunctive relief. In support thereof, Plaintiffs state as follows:

INTRODUCTION

1. Like thousands of children born every year, Baby J.W.L.B. was born addicted to opioids. Prenatal exposure to opioids causes severe withdrawal symptoms and lasting developmental impacts. The first days of Baby J.W.L.B.'s life were spent in excruciating pain as doctors weaned the infant from opioid addiction. Baby J.W.L.B. will require years of treatment and counseling to deal with the effects of prenatal exposure. Baby J.W.L.B. and their mother are victims of the opioid crisis that

has ravaged Oklahoma, causing immense suffering to those born addicted to opioids and great expense to those forced to deal with the aftermath.

2. At birth, Baby J.W.L.B. was diagnosed with Neonatal Abstinence Syndrome ("NAS"), a condition suffered by babies of mothers addicted to opioids. Baby J.W.L.B. was forced to endure a painful start to their life; crying excessively, arching their back, refusing to feed, and shaking. NAS is a clinical diagnosis, and "a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy."[1] Baby J.W.L.B. spent their first days in a Neonatal Intensive Care Unit writhing in agony as they went through detoxification.

3. Baby J.W.L.B.'s mother was prescribed Defendants' opioids prior to Baby J.W.L.B.'s gestation, resulting in her opioid addiction and Baby J.W.L.B.'s opioid exposure during gestation.

4. Upon information and belief, J.W.L.B.'s mother consumed opioids manufactured and distributed by all named defendants including:

a. Purdue's products Oxycontin, Dilaudid, and MS Contin;

b. Cephalon's products Actiq and Fentora;

c. Janssen's product Duragesic;

d. Endo's products Perodan, Percoset, Opana, Opana ER, Oxycodone, Hydrocodone (Vicodin and Lortab), Oxymorphone, and Hydromorphone; and

e. Activis' product Norco and Kadian.

5. Baby J.W.L.B.'s experience is part of an opioid epidemic sweeping through the United States, including Oklahoma, that has caused thousands of infants great suffering and continuing developmental issues. This epidemic is the largest health care crisis in U.S. history. Plaintiffs bring this class action to eliminate the hazard to public health and safety caused by the opioid epidemic and

[1] Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome,* 134(2) Pediatrics 547, 547-48 (2014), *available at* http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf.

to abate the nuisance caused by Defendants' false, negligent and unfair marketing and/or unlawful diversion of prescription opioids. Plaintiffs further seek the equitable relief of medical monitoring to provide this class of infants the monitoring of developmental issues that will almost inevitably appear as they grow older and equitable relief in the form of funding for services and treatment.

Neonatal Abstinence Syndrome

6. Many of the victims of the Opioid Crisis are babies born with Neonatal Abstinence Syndrome. It is suspected that NAS babies experience DNA changes at the cellular level, particularly in the tissues of the brain and nervous system, and may suffer lifelong afflictions as a result of maternal use of prescription opioid medications during gestation. These patients often require extensive care because they are likely to experience lifelong mental health problems, developmental impairment, and physical health limitations.

7. Recently, there has been a dramatic increase in the number of fetuses that have been exposed to opioids. Women are also victims of the opioid epidemic, and health care for opioid exposed mothers and their babies is a major factor in the nation's rising unreimbursed healthcare costs.

8. The number of infants born suffering from this insidious condition is staggering. The incidence of NAS in the United States grew five-fold between 2000 and 2012. Specifically, cases of NAS increased nationally from a rate of 1.2 per 1000 hospital births per year in 2000 to 5.8 per 1000, with a total of 21,732 infants diagnosed by 2012. Currently, the best estimates are that a child with NAS is born every 25 minutes, perhaps every 15 minutes.

9. In 2011, The Substance Abuse Mental Health Services Administration reported that 1.1% of pregnant women abused opioids (0.9% used opioid pain relievers and 0.2% used heroin).

10. In 2014, the number of babies born drug-dependent had increased by 500 percent since 2000, and children being placed in foster care due in part to parental drug abuse are going up —

now it is almost a third of all child removals.

11. Heroin and other opioid misuse during pregnancy are also associated with increased risks and incidence of placental abruption, preterm labor, maternal obstetric complications, maternal mortality, and fetal death.

12. NAS-diagnosed children "are at increased risk for neuropsychological function." The challenges presented to them and their caregivers at birth are summarized as: "Do they catch up, remain at a disadvantage, or do they proceed to function even more poorly than their peers over time?" Unfortunately, the new research borne about as a result of the Opioid Epidemic reveals that all children exposed to opioids and other drugs *in utero* are at a substantially higher risk for lower mental abilities and more signs of attention deficits," and that these effects will persist or worsen through adolescence."

13. Specifically, children diagnosed with NAS exhibit:

- by age 1: diminished performance on the Psychomotor Development Index, growth retardation, poor fine motor skills, short attention span, intellectual performance;
- between ages 2-3: significantly lower cognitive abilities, including lower motor development, lower IQ, and poor language development;
- between ages 3-6: significant detrimental impact on self-regulation, including aggressiveness, hyperactivity, lack of concentration, lack of social inhibition, lower IQs (8-15 point difference), poor language development, and behavioral and school problems; and
- after 8.5 years: significantly greater difference in cognitive scores than at previous ages, especially in girls.

14. While the pathophysiological mechanism of opioid withdrawal in neonates is currently not known, several factors can affect the accumulation of opioids in the fetus. Opiate drugs have low molecular weights, are water soluble, and are lipophilic substances; hence, they are easily transferable

across the placenta to the fetus. It is known that the transmission of opioids across the placenta increases as gestation increases. It is also known that synthetic opiates cross the placenta more easily compared with semisynthetic opiates. The combination of cocaine or heroin with methadone further increases the permeability of methadone across the placenta. Together, the ease with which these drugs can cross the blood-brain barrier of the fetus, and the prolonged half-life of these drugs in the fetus may worsen the withdrawal in infants. Neonatal abstinence syndrome is the end result of the sudden discontinuation of prolonged fetal exposure to opioids.

15. NAS babies' mothers purchase and consume prescription opioids from one or more Defendants, directly or foreseeably but indirectly, or obtain them from other sources. Each minor child suffers, and will suffer, lifelong mental illness, mental impairment, and loss of mental capacity. The minor child's entire health, use of the child's body and mind, and life, including the minor child's ability to live normally, learn and work normally, enjoy relationships with others, and function as a valuable citizen, child, parent, income-earner, and person enjoying life, are compromised, and permanently impaired.

16. Plaintiff's experience is part of an opioid epidemic sweeping through the United States and Oklahoma, causing thousands of infants great suffering and continuing developmental physical, medical, occupational, and psychological issues. This epidemic is reportedly the largest health care crisis in U.S. history. Plaintiffs bring this class action to eliminate the hazard to public health and safety caused by the opioid epidemic and to abate the nuisance caused by Defendants' false, negligent and unfair marketing and/or unlawful diversion of prescription opioids. Plaintiffs further seek equitable relief in the form of medical monitoring, in order to provide this class of infants with monitoring of developmental issues confronting them as they mature, in addition to equitable relief in the form of funding for services and treatment. The ongoing and robust medical monitoring and treatment of opioid-related NAS-diagnosed children is medically necessary. Further, this is a rapidly

transforming field, as multiple members of multiple disciplines and support systems, ranging from medical providers to psychologists to behavioral therapists to childcare providers, are coming together to determine the best protocols for improving the outcomes after a diagnosis.

17. The ongoing and robust medical monitoring and treatment of opioid-related NAS-diagnosed children is medically necessary. Medical monitoring is a rapidly transforming, as multiple members of multiple disciplines and support systems, ranging from medical providers to psychologists to behavioral therapists to childcare providers, are coming together to determine the best protocols for improving the outcomes after a diagnosis. Programs in some areas offer, for example, a view of necessary treatment components after hospital discharge: (1) education of caregivers for techniques to relieve infant distress, including infant massage, calming techniques, and other coping skills; (2) education of caregivers about NAS and the associated symptoms; (3) frequent follow-up of the infant for growth and weight gain; and(4) monthly development evaluations during infancy and toddler years to determine whether additional interventions and treatment are necessary.

18. Neonatal exposure to opioids necessarily results in medical needs that exist throughout the entire period of a child's adolescent development. These needs absolutely exist, regardless of the dosage any one child received prenatally or how he or she was weaned from these substances. These needs relate primarily to the well-known adverse effect of opioids on behavioral and regulatory development in exposed children. Every single child diagnosed with opioid-related NAS must have robust medical testing, monitoring, intervention, provision of caregiver training and information, and medical referral in order to maximize his or her future as an adult. This relief will also largely abate the public nuisance created by Defendants' conduct. For this reason, Plaintiff and the class seek, inter alia, injunctive relief.

19. In recent years, there has been a dramatic rise in the proportion of infants who have been exposed to opioids. Opioid use among women who gave birth increased in the United States

from 1.19 to 5.63 per 1,000 hospital births per year between 2000 and 2009. Concurrently the incidence of neonatal abstinence syndrome (NAS) among newborns increased during the same period (from 1.20 per 1,000 hospital births per year in 2000 to 3.39 per 1,000 hospital births per year in 2009).[2]

20. In a study from Florida, the number of newborns who had NAS and were admitted to the NICU increased by 10-fold from 2005 to 2011. Increases in the incidence of NAS have been reported uniformly across community hospitals, teaching hospitals, and children's hospitals.[3]

21. The incidence of NAS in newborns born to opioid-dependent women is between 70 and 95 percent. Research suggests that newborns with NAS (most commonly associated of opioid misuse during pregnancy) are more likely than all other hospital births to have low birthweight or respiratory complications. Untreated heroin and other opioid misuse during pregnancy also is associated with increased risk of placental abruption, preterm labor, maternal obstetric complications, and fetal death.[4]

22. The NAS epidemic and its consequences could have been, and should have been, prevented by the Defendants who control the U.S. drug distribution industry and the Defendants who manufacture the prescription opioids. These Defendants have profited greatly by allowing Oklahoma to become flooded with prescription opioids.

23. The drug distribution industry is supposed to serve as a "check" in the drug delivery

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[2] Patrick, S. W., Schumacher, R. E., Benneyworth, B. D., Krans, E. E., McAllister, J. M., & Davis, M. M. (2012). Neonatal abstinence syndrome and associated health care expenditures: United States, 2000–2009. *Journal of the American Medical Association, 307*(18), 1934–1940.

[3] Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome,* 134(2) Pediatrics 547, 547-48 (2014), *available at* http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf.

[4] Winklbaur, B., Kopf, N., Ebner, N., Jung, E., Thau, K., & Fischer, G. (2008). *Treating pregnant women dependent on opioids is not the same as treating pregnancy and opioid dependence.* Addiction, 103(9), 1429–1440; *see also* American College of Obstetricians and Gynecologists. (2012; reaffirmed in 2014). Opioid abuse, dependence, and addiction in pregnancy (Committee Opinion No. 524). Retrieved from http://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co524.pdf?dmc=1&ts=20150928T1302076021; *see also* Kaltenbach, K., Berghella, V., & Finnegan, L. (1998). Opioid dependence during pregnancy: Effects and management. Obstetrics Gynecology Clinics of North America, 25(1), 139–151.

system, by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. Defendants woefully failed in this duty, instead consciously ignoring known or knowable problems and data in their supply chains.

24. Defendants thus intentionally and negligently created conditions in which vast amounts of opioids have flowed freely from drug manufacturers to innocent patients who became addicted, to opioid abusers, and even to illicit drug dealers - with distributors regularly fulfilling suspicious orders from pharmacies and clinics, who were economically incentivized to ignore "red flags" at the point of sale and before dispensing the pills.

25. Defendants' wrongful conduct has allowed billions of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in Oklahoma. This is characterized as "opioid diversion." Acting against their common law and statutory duties, Defendants have created an environment in which opioid diversion is rampant. As a result, unknowing patients and unauthorized opioid users have ready access to illicit sources of diverted opioids.

26. For years, Defendants and their agents have had the ability to substantially reduce the consequences of opioid diversion, including the dramatic increase in the number of infants born with NAS. All the Defendants in this action share responsibility for perpetuating the epidemic and the exponential increase in the number of infants afflicted with NAS.

27. Defendants have foreseeably caused damages to Baby J.W.L.B. and Class Members including the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiffs bring this civil action for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors,

retailers, and manufacturers that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably injured, and continues to injure, Plaintiff Baby J.W.L.B. and the Class.

PARTIES

A. Plaintiffs

28. Baby J.W.L.B., a citizen of Oklahoma, and Putative Class members are individuals who have suffered Neonatal Abstinence Syndrome as a result of exposure to opioids in utero. This drug exposure provides Baby J.W.L.B. the right to sue, through their next friend and guardian, for damages under product liability, nuisance, negligence, and gross negligence.

29. Baby J.W.L.B. and Putative Class Members directly and foreseeably sustained all damages alleged herein. Categories of past and continuing sustained damages include, inter alia: (1) costs for providing treatment of infants born with opioid-related medical conditions like NAS; (2) equitable relief of medical monitoring, testing and treatment for latent dread diseases associated with NAS (3) costs for providing ongoing medical monitoring care into a Court administered fund, additional therapeutic and prescription drug purchases, and other treatments; (4) costs for providing treatment, counseling and rehabilitation services; and (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care services.

30. Baby J.W.L.B. and the Putative Class Members have suffered and continue to suffer these damages directly. Plaintiffs and Putative Class Representatives also seek the means to abate the epidemic Defendants' wrongful and/or unlawful conduct has created.

B. Defendants

Distributor Defendants

31. McKesson Corporation ("**McKesson**") has its principal place of business in San

Francisco, California and is incorporated under the laws of Delaware. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in the State of Oklahoma.

32. Cardinal Health, Inc. ("**Cardinal**") has its principal place of business in Ohio and is incorporated under the laws of Ohio. During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in the State of Oklahoma.

33. AmerisourceBergen Corporation has its principal place of business in Pennsylvania and is incorporated under the laws of Delaware. During all relevant times, **AmerisourceBergen** has distributed substantial amounts of prescription opioids to providers and retailers in the State of Oklahoma.

34. Defendant CVS Health Corporation ("**CVS**") is a Delaware corporation with its principal place of business in Rhode Island. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. CVS also operates retail stores in numerous States, including in Oklahoma, that sell prescription medicines, including opioids. At all times relevant to this Amended Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Oklahoma.

35. Defendant Rite Aid of Maryland, Inc., dba Rite Aid Mid-Atlantic Customer Support Center, Inc. is a Maryland corporation with its principal offices located in Lutherville Timonium, Maryland. Defendant Rite Aid Corp. is a Delaware corporation with its principal offices located in Camp Hill, Pennsylvania. Together, Rite Aid of Maryland, Inc. and Rite Aid Corp. are referred to as "**Rite Aid**."

36. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite-Aid also operates retail stores, including in Oklahoma, that sell prescription medicines, including opioids. At all times relevant to this Complaint,

Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Oklahoma.

37. Defendant Walgreens Boots Alliance, Inc., is a Delaware corporation with its principal place of business in Illinois. Defendant Walgreen Eastern Co. is a subsidiary of Walgreens Boots Alliance, Inc. that is engaged in the business of distributing pharmaceuticals, including prescription opioids. Defendant Walgreen, Co. is a subsidiary of Walgreens Boots Alliance that operates retail drug stores. Together, Walgreens Boots Alliance, Inc., Walgreen Eastern Co. and Walgreen Co. are referred to as "**Walgreens**."

38. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all relevant times, Walgreens has sold and continues to sell prescription opioids in close proximity to the hospitals, clinics, and other healthcare facilities serving the state of Oklahoma.

39. Defendant Wal-Mart Inc. f/k/a Walmart Stores, Inc. ("**Wal-Mart**"), is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Walmart, through its various DEA registered affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Amended Complaint, Wal-Mart distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Oklahoma.

40. Defendant MIAMI-LUKEN, INC. ("**Miami-Luken**") is an Ohio corporation with its principal place of business located in Springboro, Ohio. During all relevant times, Miami-Luken has distributed substantial amounts of prescription opioids to providers and retailers in Oklahoma.

41. Defendant COSTCO WHOLESALE CORPORATION ("**Costco**") is a Washington corporation with its principal place of business in Issaqua, Washington. During all relevant times, Costco has sold and continues to sell, in Oklahoma and nationwide, prescription opioids including

the Opioid Drugs at issue in this lawsuit.

42. Defendant The Kroger Co. ("**Kroger**) is an Ohio corporation with headquarters in Cincinnati, OH. Kroger operates 2,268 pharmacies in the United States. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in Oklahoma.

43. Defendants H. D. Smith, LLC d/b/a HD Smith f/k/a H. D. Smith Wholesale Drug Co., H. D. Smith Holdings, LLC, H. D. Smith Holding Company ("**H. D. Smith**") is a Delaware corporation with its principal place of business in Springfield, Illinois. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic, and specialty pharmaceuticals. At all times relevant to this Complaint, H. D. Smith distributed prescription opioids throughout the United States, including Oklahoma.

44. Defendant Anda, Inc. ("**Anda**"), is a Florida corporation with its principal office located in Olive Branch, Mississippi. Through its various DEA registrant subsidiaries and affiliated entities, Anda is the fourth largest distributor of generic pharmaceuticals in the United States, which includes Oklahoma State. In October 2016, Defendant Teva USA acquired Anda for $500 million in cash. At all relevant times, Anda distributed prescription opioids throughout the United States, including in Oklahoma.

45. McKesson, Cardinal, AmerisourceBergen, CVS, Rite Aid, Walgreens, Wal-Mart, Miami-Luken, Costoco, Kroger, H.D. Smith, and Anda are collectively referred to hereinafter as "**Distributor Defendants**."

Pharmaceutical Marketing and Manufacturing Defendants

46. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Oklahoma. Actiq and Fentora have been approved by the FDA

only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

47. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly- owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

48. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the U.S. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S. through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Oklahoma, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Oklahoma, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own. Through interrelated operations like these, Teva Ltd. operates in Oklahoma and the rest of the U.S. through its subsidiaries Cephalon and Teva USA. The U.S. 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 Oklahoma 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 Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as "**Cephalon**.")

49. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals 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 hereinafter are collectively referred to as "**Janssen**."). Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Oklahoma, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

50. 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. hereinafter are collectively referred to as "**Endo**.") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Oklahoma. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion

in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Oklahoma, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

51. 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, later to 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 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 Oklahoma. Upon information and belief, Allergan PLC exercises control over and derives financial benefit from the marketing, sales, and profits of Allergan/Actavis products. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are referred to collectively as "**Actavis**.") 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 Oklahoma. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

52. Defendant DEPOMED, INC. ("**Depomed**") is a California corporation with its

principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets, and sells prescription drugs in Oklahoma and nationally. Depomed acquired the rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015 Asset Purchase Agreement. This agreement closed on April 2, 2015.

53. Defendant Mallinckrodt LLC is a Delaware corporation with its headquarters in Hazelwood, Missouri. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt is engaged in the manufacture, promotion, distribution, and sale of opioids such as Roxicodone, Exalgo, Xartemis XR, as well as oxycodone and other generic opioids. MPLC also operates under the registered business name Mallinckrodt Pharmaceuticals ("MPMO"), with its U.S. headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, "**Mallinckrodt**") manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

54. Defendant Par Pharmaceutical, Inc. is a New York corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies,

Inc. are referred to collectively as "**Par Pharmaceutical**"). Par Pharmaceutical is an affiliate of Defendants Endo Health Solutions Inc. ("EHS") and Endo Pharmaceuticals, Inc. ("EPI). EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, "Endo"), manufacture opioids sold throughout the United States including in Oklahoma.

55. Defendant Noramco, Inc. ("**Noramco**") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

56. Defendant Invidior, Inc. ("**Invidior**") is a Delaware domestic corporation with its principal place of business in Richmond, Virginia. Indivor manufactures and distributes buprenorphine-based prescription drugs for treatment of opioid dependence. Buprenorphine is a Schedule III drug. The company offers medication under the brand name Suboxone and sublingual tablets under the brand name Subutex. Indivor, Inc. is a subsidiary of Indivor, PLC, based in the United Kingdom. Indivor, Inc. was formerly known as Reckitt Benckiser Pharmaceuticals, Inc. Indivor, Inc. has manufactured and/or labeled Buprenorphine shipped to Oklahoma.

Purdue Defendants

57. 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**"). Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and Oklahoma. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

58. Defendant Richard S. Sackler is a natural person residing in Travis County, Texas. He is a son of Raymond Sackler and, beginning in the 1990's, served as a member of the Board of Directors of Purdue and Purdue-related entities.

59. Defendant Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut and, upon information and belief, New York State. He is a son of Raymond Sackler and has been a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

60. Defendant Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Mortimer Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

61. Defendant Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut, and, upon information and belief, New York State. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

62. Defendant Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

63. Defendant Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Raymond Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

64. Defendant Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

65. Defendant David A. Sackler is a natural person residing in New York County, New

York. He is the son of Richard Sackler (and thus grandson of Raymond Sackler) and has served as a member of the board of directors of Purdue and Purdue related entities since 2012.

66. Defendant Rhodes Technologies ("Rhodes Tech") is a Delaware general partnership formed on April 12, 2005 with its principal place of business in Coventry, R.I. At relevant times, Rhodes Tech or its predecessor has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations.

67. Defendant Rhodes Technologies Inc. ("Rhodes Tech Inc.") is a Delaware corporation formed January 28, 1999 with its principal place of business in Coventry, R.I. Rhodes Tech Inc. is a general partner of Rhodes Tech. At relevant times, Rhodes Tech Inc. has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations or has managed Rhodes Tech or its predecessor in doing so.

68. Defendant Rhodes Pharmaceuticals L.P. ("Rhodes Pharma") is a Delaware limited partnership formed November 9, 2007 with its principal place of business in Coventry, R.I. At all relevant times, Rhodes Pharma has marketed a generic form of OxyContin manufactured by Purdue Pharmaceuticals L.P. ("PPNC"), a Delaware limited partnership that is also a subsidiary of Defendant PPLP; PPNC owns and operates a pharmaceutical manufacturing facility in Wilson, North Carolina.

69. Defendant Rhodes Pharmaceuticals Inc. ("Rhodes Pharma Inc.") is a New York corporation formed on November 9, 2007. Rhodes Pharma Inc. is a general partner of Rhodes Pharma. At all relevant times, Rhodes Pharma Inc. has marketed a generic form of OxyContin being manufactured by PPNC.

70. Defendant Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust") is a trust of which Defendants Beverly Sackler, Richard S. Sackler, and/or Jonathan D. Sackler are trustees.

71. The Raymond Sackler Trust is a direct or indirect beneficial owner of 50% of Purdue as well as the recipient of 50% of the profits of Rhodes Pharma Inc.

72. Defendant The P.F. Laboratories, Inc. ("PF Labs") is a New Jersey corporation with its principal place of business located in Totowa, New Jersey. It was, at relevant times, engaged in the business of manufacturing OxyContin for Purdue. At all relevant times, PF Labs has been beneficially owned, managed, and controlled by Sackler Family Defendants.

73. The Raymond Sackler Trust is a direct or indirect beneficial owner of 50% of Purdue as well as the recipient of 50% of the profits of PF Labs.

74. Each of the foregoing Purdue Defendants are referred to collectively as the Purdue Defendants and are included collectively in the term "**Purdue**," and collectively in the allegations, claims and causes of action against "Purdue" and "Pharmaceutical Defendants."

75. Purdue, Cephalon, Janssen, Endo, Actavis, Depomed, Mallinckrodt, Par Pharmaceutical, Noramco, and Invidior are collectively referred to hereinafter as the "**Pharmaceutical Defendants**" or "**Marketing and Manufacturing Defendants**."

JURISDICTION AND VENUE

76. This Court is vested with jurisdiction by virtue of the Class Action Fairness Act, 28 U.S.C. § 1332(d). Minimal diversity exists between named Plaintiff of this putative class action, a citizen of the State of Oklahoma, and Defendants. The proposed class exceeds 100 persons. Further, the amount in controversy exceeds $5,000,000.00, as the value of the benefit to the Class will exceed $5,000,000. The typical post birth hospital admission cost for one NAS baby is $180,000 to $250,000. Thus the admission costs of as few as 20 NAS babies may exceed $5,000,000. Babies afflicted with NAS are born every 15 minutes.

77. This Court has personal jurisdiction over Defendants, each of which has committed

torts, in part or in whole, within the State of Ohio, as alleged herein. Moreover, Defendants have substantial contacts and business dealings directly within Ohio by virtue of their distribution, dispensing, and sales of prescription opioids.

78. Venue is proper in this Court pursuant to this Court's Case Management Order One (Doc. 232) allowing direct filing into these MDL proceedings. Plaintiff reserve the right to move for transfer at the conclusion of pretrial proceedings.

79. Per Case Management Order One, Plaintiff does not concede that Ohio law applies by directly filing in this MDL proceeding.

BACKGROUND FACTS

80. Opioid means "opium – like" and the term includes all drugs derived in whole or in part from the opium poppy.

81. The United States Food and Drug Administration's website describes this class of drugs as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."

82. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the Controlled Substances Act. They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

83. Before the epidemic of Defendants' prescription opioids, the generally accepted standard of medical practice was 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.

PHARMACEUTICAL DEFENDANTS' WRONGFUL CONDUCT

84. To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and negligent marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread misrepresentations about the risks and benefits of long-term opioid use – statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including those in Oklahoma.

85. The Pharmaceutical Defendants spread their false and negligent statements by marketing their branded opioids directly to doctors and patients in Oklahoma. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of Oklahoma.

86. The Pharmaceutical Defendants' direct and branded ads negligently portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief

and functional improvement. Purdue ran a series of ads, called "Pain Vignettes," for OxyContin that 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. While Endo and Purdue agreed in 2015-16 to stop these particularly misleading representations in New York, they continued to disseminate them in Oklahoma.

87. The Pharmaceutical Defendants also promoted the use of opioids for chronic pain through "detailers" – sophisticated and specially trained sales representatives who visited individual doctors and medical staff, and fomented small-group speaker programs. In 2014, for instance, these Defendants spent almost $200 million on detailing branded opioids to doctors.

88. The FDA has cited at least one of these Defendants for negligent promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

89. The Pharmaceutical Defendants invited doctors to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. 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 these 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.

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

91. The Pharmaceutical Defendants have had unified marketing plans and strategies from state to state, including Oklahoma. This unified approach ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.

92. The Pharmaceutical Defendants negligently marketed opioids in Oklahoma through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents.

93. The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the negligent messages came from an independent and objective source.

94. The Pharmaceutical Defendants' negligent unbranded marketing also contradicted their branded materials reviewed by the FDA.

95. The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

96. These Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

97. The Pharmaceutical Defendants collaborated, through the aforementioned organizations and groups, to spread negligent messages about the risks and benefits of long-term opioid therapy.

98. To convince doctors and patients in Oklahoma that opioids can and should be used to treat chronic pain, these Defendants had to persuade them that long-term opioid use is both safe and helpful. Knowing that they could do so only by conveying negligent misrepresentations to those doctors and patients about the risks and benefits of long-term opioid use, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

99. To convince doctors and patients that opioids are safe, the Pharmaceutical Defendants negligently 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: (a) starting patients on opioids was low- risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose

special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

100. The Pharmaceutical Defendants negligently claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these negligent misrepresentations by opioid manufacturers are: (a) Actavis employed a patient education brochure that negligently claimed opioid addiction is "less likely if you have never had an addiction problem;" (b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, negligently claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which negligently claimed that "[p]eople who take opioids as prescribed usually do not become addicted;" (d) Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "most people do not develop an addiction problem;" (e) Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as "myth" the claim that opioids are addictive; (f) a Janssen website negligently claimed that concerns about opioid addiction are "overestimated;" (g) Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management – that negligently claims that pain is undertreated due to "misconceptions about opioid addiction."

101. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for three (3)

months substantially increases risk for opioid use disorder."

102. The FDA further exposed the falsity of the Pharmaceutical Defendants' claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013 and for other 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. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

103. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." 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 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. This agreement, however, did not extend to Oklahoma.

104. The Pharmaceutical Defendants negligently instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudo-addiction" – a term used by Dr. David Haddox, who went to work for Purdue, and Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and

Purdue. Defendants negligently claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these negligent claims are: (a) Cephalon and Purdue sponsored Responsible Opioid Prescribing, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated;" (c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudo-addiction by teaching that a patient's aberrant behavior was the result of untreated pain; (d) Purdue sponsored a negligent CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse in which a narrator notes that because of pseudo-addiction, a doctor should not assume the patient is addicted.

105. The 2016 CDC Guideline rejects the concept of pseudo-addiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer- term use," and that physicians should reassess "pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

106. The Pharmaceutical Defendants negligently instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Pharmaceutical Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Pharmaceutical Defendants' misrepresentations were intended to make doctors more comfortable in prescribing opioids. Some examples of these negligent claims are: (a) an Endo

supplement in the Journal of Family Practice emphasized the effectiveness of screening tools to avoid addictions; (b) Purdue's webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths;" (c) Purdue represented in scientific conferences that "bad apple" patients – and not opioids – were the source of the addiction crisis, when in fact the "bad apples" were the Defendants.

107. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." The Guideline emphasizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

108. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Pharmaceutical Defendants negligently claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

109. A CME sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, that claimed "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," without mentioning any known or foreseeable issues.

110. Pharmaceutical Defendants negligently minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia,

abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

111. The Pharmaceutical Defendants negligently claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences, and failed to disclose the greater risks to patients at higher dosages. 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. For example: (a) an Actavis patient brochure 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;" (b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, claiming that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain; (c) an Endo website, painknowledge.com, claimed that opioid dosages may be increased until "you are on the right

dose of medication for your pain;" (d) an Endo pamphlet Understanding Your Pain: Taking Oral Opioid Analgesics, stated "The dose can be increased. . . . You won't 'run out' of pain relief;" (e) a Janssen patient education guide Finding Relief: Pain Management for Older Adults listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages; (f) Purdue's In the Face of Pain website promotes 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's A Policymaker's Guide to Understanding Pain & Its Management stated that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages; (h) a Purdue CME entitled Overview of Management Options taught that NSAIDs and other drugs, but not opioids, were unsafe at high dosages; (i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

112. These and other representations conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

113. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose

mortality."

114. Pharmaceutical Defendants' marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

115. Pharmaceutical Defendants have 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 negligently claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

116. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." New York found those statements false and negligent because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

117. These numerous, longstanding misrepresentations minimizing the risks of long-term opioid use persuaded doctors and patients to discount or ignore the true risks. Pharmaceutical Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a

long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants negligently and misleadingly touted the benefits of long-term opioid use and negligently and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and negligent claims, they continue to make them today.

118. For example, the Pharmaceutical Defendants negligently claimed that long-term opioid use improved patients' function and quality of life, including the following misrepresentations: (a) an Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives; (b) an Endo advertisement that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks, portraying seemingly healthy, unimpaired persons; (c) a Janssen patient education guide Finding Relief: Pain Management for Older Adults stated as "a fact" that "opioids may make it easier for people to live normally" such as sleeping peacefully, working, recreation, sex, walking, and climbing stairs; (d) Purdue advertisements of OxyContin entitled "Pain vignettes" implied that OxyContin improves patients' function; (e) Responsible Opioid Prescribing, by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function; (f) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain counseling patients that opioids "give [pain patients] a quality of life we deserve;" (g) Endo's NIPC website painknowledge.com claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies,

that you were not able to enjoy when your pain was worse;" (h) Endo CMEs titled Persistent Pain in the Older Patient claimed that chronic opioid therapy had been "shown to reduce pain and improve depressive symptoms and cognitive functioning;" (i) Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function;" (j) Purdue's A Policymaker's Guide to Understanding Pain & Its Management claimed that "multiple clinical studies" had shown opioids as effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients; (k) 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.

119. These claims find no support in the scientific literature. The 2016 CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely" (emphasis added). The CDC reinforced this conclusion throughout its 2016 Guideline:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

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

121. The 2016 CDC Guideline was not the first time a federal agency repudiated the

Pharmaceutical Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." In 2008, 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."

122. The Pharmaceutical Defendants also negligently 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 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." The 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

123. In addition, 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 relevant times. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is

known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and negligent, 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.

124. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue negligently promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

125. Cephalon negligently 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.

126. 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, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false

impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain; (b) 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; and (c) in December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

127. Cephalon's negligent 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.

128. Purdue 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 until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

129. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

130. 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.

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

132. The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly

addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned these Defendants of this, and these Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

133. Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their negligent marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the negligent marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and negligent statements about the risks and benefits of long-term opioid use for chronic pain.

134. The Pharmaceutical Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, fake independent 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 Pharmaceutical Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

135. Finally, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. These Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for these Defendants' negligent messages was not apparent to medical professionals who relied upon them in making treatment decisions.

136. Thus, the Pharmaceutical Defendants successfully concealed from the medical community, municipalities, patients, and health care payers facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert. Plaintiffs 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.

137. The Pharmaceutical Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

138. The Pharmaceutical Defendants' negligent marketing scheme caused and continues to cause doctors in Oklahoma to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent these Defendants' negligent marketing scheme, these doctors would not have prescribed as many opioids. These Defendants' negligent marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' negligent marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be

using less of them.

139. The Pharmaceutical Defendants' negligent marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their negligent marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

140. The escalating number of opioid prescriptions written by doctors who were deceived by the Pharmaceutical Defendants' negligent marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Oklahoma. In August 2016, the U.S. Surgeon General published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to negligent marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

141. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

142. Contrary to the Pharmaceutical Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the

internet. Numerous doctors and substance abuse counselors note that many of their patients, who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

Depomed

143. Depomed sales representatives misrepresented the safety and efficacy of its opioid drugs to physicians. Depomed has, since at least October 2011, engaged in unsafe and/or unapproved marketing of Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER.

144. Depomed sales representatives promoted Lazanda for unsafe and unapproved uses.

145. Lazanda is only indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." Despite the drug's explicit limitation, Depomed actively promoted Lazanda to physicians who do not treat cancer patients. Not only did Depomed instruct sales representatives to promote Lazanda to non-cancer treating physicians, the Company also discouraged sales representatives from marketing the drug to physicians treating cancer patients, even if the sales representatives were successful in gaining these doctors' business.

146. When it launched Lazanda in 2011, the Company's management, from the start, disregarded the FDA's limitations concerning Lazanda's usage, instructing its sales representatives to target pain management physicians, particularly those who historically wrote large numbers of ROOs and Lazanda-like drugs.

147. Sales representatives were pressured to target pain management physicians. Area managers at Depomed regularly supplied sales representatives with lists of target physicians containing few, if any, physicians treating cancer patients. Of the typical call list containing approximately 100 physicians, under five generally treated cancer patients.

148. Depomed also strongly discouraged sales representatives from targeting physicians treating cancer patients. Sales representatives had to "make a case" for using any portion of their allotted marketing money to call on cancer treating physicians. And employees who did call on cancer treating physicians were disciplined.

149. One Depomed sales representative, who worked in the Los Angeles area, was chastised by management for targeting, almost exclusively, physicians treating cancer patients despite the fact that he had been very successful in generating business from these physicians. This representative was reprimanded for targeting physicians who could prescribe Lazanda for its indicated use, and was told to stop targeting these physicians, and to think about how well he could be doing if he was targeting potentially higher writerDepomed explicitly told sales representatives to market only to non-cancer treating physicians by their managers, most notably Todd Wittenbach, the company's then head of sales for the United States.

150. Depomed sales representatives were also trained to deal with (rightful) pushback from physicians. For example, when confronted with the common statement from a physician that "it's extremely rare that we see cancer patients," Depomed trained sales representatives to divert the conversation to the physician's use of other, similar medications. For example, sales representatives were trained to respond by saying "well tell me about your patients taking Actiq," and then extol the relative benefits of switching those patients to Lazanda.

151. Due to the worsening headwinds within the opioid market, Depomed ultimately sold Lazanda to Slán Medicinal Holdings on November 7, 2017.

152. Depomed sales representatives promoted Nucynta and Nucynta ER for unsafe and unapproved uses.

153. On April 2, 2015, Depomed acquired from Janssen and its affiliates the U.S. rights to the Nucynta franchise of pharmaceutical products for $1.05 billion in cash. The Nucynta franchise is

an opioid that includes Nucynta ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, Nucynta IR (tapentadol), an immediate release version of tapentadol, for management of moderate to severe acute pain in adults, and Nucynta (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized.

154. Nucynta's annual sales increased in the U.S. from $189.9 million in 2015 to approximately $281.3 million in 2016, quickly becoming Depomed's best-selling product. This marked a 48% year-over-year growth in sales of Nucynta in just one year.

155. The marketing strategy causing the astronomical growth in sales, however, was fueled by Depomed's illegal practices in connection with its marketing of Nucynta for unsafe and unapproved uses. In particular, Depomed promoted the use of opioids for all manner of pain management while downplaying the drug's addictive nature, often promoting the drug as a safer alternative to opioids, despite this not being on the FDA label.

156. Further, Depomed promoted an increase in dosage while focusing on family physicians and internal medicine doctors who were less knowledgeable about the dangers of opioids. In February 2017, Depomed's former CEO increased its sales force for the specific purpose of targeting primary care physicians.

157. The FDA-approved labels for both Nucynta IR and Nucynta ER describe the tapentadol molecule as "a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone." Nowhere on the FDA-approved label does it say or mention that Nucynta is safer, more tolerable, less abusive, or less addictive than other opioids. Despite this, Nucynta has a long history of its manufacturer (formerly Janssen) claiming these benefits in its sales pitches and marketing.

158. Nonetheless, Depomed directed its sales representatives to market Nucynta for unsafe and unapproved uses as a safer, less abusive, less addictive opioid that did not create the same euphoric feeling as other opioids, even though this was not on the FDA-approved label.

159. Depomed management knew that the FDA-approved label for Nucynta contained no information about it being safer, more tolerable, less addictive, or less abusive than alternative opioids, and knew they could not market Nucynta this way. 245. On June 23, 2015 investor call, August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that "[a]lthough not in the label, there's a very low abuse profile and side effect rate."

160. Additionally, in a March 14, 2015 presentation at the ROTH Conference, then Depomed CEO Schoeneck stated: "The addiction profile is thought to be better. I can't make a claim around that because we don't actually have that in the label." In February 2017, Schoeneck also told investors that Depomed was "initiating label enhancement studies, aimed at further differentiating Nucynta by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace." The purpose of this was to "be able to get it hopefully into the label."

161. Depomed's marketing push was "Think Differently." Sales representatives were told that Nucynta is a "safer opioid." They were told to tell physicians about Nucynta and its value to patients in terms of, among other things, improved safety relative to other opioids on the market.

162. Depomed actively targeted primary care physicians with marketing presentations that described Nucynta as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market Nucynta in this manner, and also did not have any independent scientific evidence to support these claims.

163. Depomed represented that Nucynta was uniquely positioned to combat the negative public sentiment against Opioids. Former President and CEO James Schoeneck described to investors

that Nucynta had "different properties than the other opioids, particularly when it comes to the kind of activity that the CDC and others are most concerned about" and that "there'll be relatively little impact on [Depomed] compared to where some other companies may fall in at."

164. Depomed knew that it could not promote Nucynta as a safer, less addictive, less abusive opioid that did not have the same euphoric feeling on patients because these properties were not on its FDA-approved label. Despite this knowledge, Depomed trained its sales representatives to use these marketing tactics to sell Nucynta, using the same sales team as Janssen had to promote Nucynta, knowing that Janssen was being sued for, among other things, improperly marketing Nucynta.

165. Due to the worsening headwinds within the Opioid market, Depomed ultimately entered into a commercialization agreement with Collegium Pharmaceutical, Inc., for the NUCYNTA brand on December 4, 2017.

Mallinckrodt

166. In Oklahoma and nationwide, Mallinckrodt is engaged in the manufacture, promotion, distribution, and sale of opioids such as Roxicodone, Exalgo, Xartemis XR, as well as oxycodone and other generic opioids.

167. Mallinckrodt engaged in widespread conduct aimed at vastly increasing profits resulting from the sale of opioid drugs by increasing prescriber demand, increasing patient demand, facilitating insurance coverage, and nurturing the thriving black market for opioid drugs by concealing evidence of drug diversion.

168. Upon information and belief, Mallinckrodt promoted the use of opioids for chronic pain through "detailers," who were sales representatives who visited individual physicians and their staff in their offices and small group speaker programs. Mallinckrodt sales representatives misrepresented the safety and efficacy of its opioid drugs to physicians.

169. Mallinckrodt provided substantial funding to purportedly neutral organizations which disseminated false messaging about opioids. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain- Topics.org, a now-defunct website that touted itself as "a noncommercial resource for HCPs, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."

170. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb ("Gottlieb"), the new commissioner of the FDA, $22,500 for a speech in London, shortly after the U.S. presidential election. Gottlieb has also received money from the HDA, an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.

171. Mallinckrodt, combined with five other opioids manufacturers, made payments exceeding $140,000 to ten members of the ACPA Advisory Board.

172. Mallinckrodt's aggressive and misleading marketing to prescribers and consumers, development of fake scientific substantiation and literature, and failure to prevent, monitor, identify, and report drug diversion, all contributed to a vast increase in opioid overuse and addiction.

173. Mallinckrodt, plc, Mallinckrodt, LLC and SpecGx, LLC and their subsidiaries are "Pharmaceutical Defendants" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Pharmaceutical Defendants in the existing complaint.

Par Pharmaceutical

174. Par Pharmaceutical is an affiliate of Defendants Endo Health Solutions Inc. ("EHS") and Endo Pharmaceuticals, Inc. ("EPI). EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, "Endo"), manufacture opioids sold throughout the United States. Plaintiffs adopt all allegations and causes of action alleged against Endo and the Pharmaceutical Defendants alleged in the existing complaint against Par Pharmaceutical.

Noramco

175. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital. All allegations pertaining to Janssen also apply to Noramco. Plaintiffs adopt all allegations and causes of action alleged against the Pharmaceutical Defendants alleged in the existing complaint against Noramco.

Invidior

176. Invidior manufactures and distributes buprenorphine-based prescription drugs for treatment of opioid dependence. Buprenorphine is a Schedule III drug. The company offers medication under the brand name Suboxone and sublingual tablets under the brand name Subutex. Indivor, Inc. has manufactured and/or labeled Buprenorphine shipped to Oklahoma. Plaintiffs adopt all allegations and causes of action alleged against the Pharmaceutical Defendants alleged in the existing complaint against Invidior.

Purdue

i. Structure of the Purdue Entities and the Roles of the Purdue-Related Defendants

177. Purdue is part of a greater, complicated web of entities through which the Sackler Families operate. PPI is the managing general partner of PPLP and of many of the various Purdue-related entities. Its status as managing general partner of the various entities ensures PPI's control of those entities. In turn, at all relevant times, all of the members of the board of PPI have been Sackler Family Defendants and Sackler-family retainers. The entities directly or indirectly related to Purdue that are not controlled by the Sackler Family Defendants through PPI are, nonetheless, controlled by the Sackler Family Defendants through different entities presently unknown to Plaintiffs. For instance, at all relevant times, the Sackler Family Defendants and the Sackler Families controlled PF Labs and Rhodes Pharma.

178. Because the Sackler Family Defendants and/or the Sackler Families control of the board of PPI, all of the officers employed by PPI and PPLP reported to them. This ensured Sackler domination and control of PPI and PPLP, even when the officers of those entities were not themselves members of the Sackler Families or Sackler Family Defendants.

179. The Sackler Family Defendants and/or Sackler Families are beneficial owners of, and exercise complete domination and control over, all four Rhodes-identified Defendants and PF Labs.

180. The Sackler Family Defendants and/or Sackler Families Sackler approved the decision to enter the generic market for OxyContin in or about 2008, and that it should do so through Rhodes Pharma, a Sackler-owned entity created for that purpose.

181. The Sackler Family Defendants and/or Sackler Families caused Purdue and other associated companies that they beneficially owned and controlled to distribute to the Sackler Families hundreds of millions of dollars of profits earned by Purdue and its associated companies from the sale of opioids.

182. Each of the Sackler Family Defendants named herein has served on the board of directors of, or as an officer of, Purdue and one or more Purdue-related business entities, like PF Labs.

183. The Sackler Family Defendants beneficially own and control all of the entities owned by the Sackler Families, including PF Labs and the Rhodes Defendants, in substantially the same way as they control PPLP and its affiliates, although they may do so using different holding companies and trusts than those used to control PPLP.

184. At all relevant times, Richard Sackler played an active and central role in the management of Purdue and the Purdue-related business entities. He began working for Purdue as Assistant to the President (his father, Raymond) in the 1970s. He later served as Vice President of Marketing and Sales. In the early 1990s he became Senior Vice President, which was the position he held at the time OxyContin was launched in 1996. In 1999, he became President, and he served in

that position until 2003.

185. Richard Sackler resigned as President in 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve, with his uncle Mortimer, as Co-Chair of the Board of Purdue. In that way, among others, the family maintained control over their family business, even though they were no longer officers, because the officers reported to them.

186. As a senior executive of Purdue, Richard Sackler was actively involved in the invention, development, marketing, promotion, and sale of Purdue's opioid products, including OxyContin. He worked tirelessly to make OxyContin a blockbuster, telling colleagues how devoted he was to the drug's success. Along with his father (Raymond) and his uncle (Mortimer), he launched OxyContin with one of the biggest pharmaceutical marketing campaigns in history, deploying many persuasive techniques pioneered by his uncle Arthur. Within five years of its introduction, OxyContin was generating a billion dollars a year. When OxyContin met with resistance, Richard participated in Purdue's efforts to counter that resistance.

187. At all relevant times, Richard Sackler served as a trustee of one or more trusts that beneficially own and control Purdue and the Purdue-related business entities.

188. Richard Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and the Purdue-related business entities named herein as additional defendants from the sale of opioids.

189. Jonathan Sackler was a Vice President of Purdue in 1991, and by 2000 he was a Senior Vice President. Like his brother Richard, he resigned that position in or after 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve on the board of Purdue.

190. At all relevant times, Jonathan Sackler served as a trustee or one or more trusts that

beneficially owns and control Purdue and the Purdue-related business entities.

191. Jonathan Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and the Purdue-related business entities from the sale of opioids.

192. Mortimer D.A. Sackler served as a Vice President of Purdue during the period of the development, launch, and promotion of OxyContin. He resigned that position in or after 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve on the Board of Purdue.

193. Mortimer D.A. Sackler is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and the Purdue-related business entities from the sale of opioids.

194. Kathe A. Sackler was a Vice President of Purdue in 1991, and by 2000 she was a Senior Vice President. She resigned that position in or about 2003 due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, she continued to serve on the Board of Purdue.

195. Kathe A. Sackler is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and the Purdue-related business entities from the sale of opioids.

196. Ilene Sackler Lefcourt served as Vice President of Purdue during the period of the development, launch, and promotion of OxyContin. She resigned that position in or after 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, she continued to serve on the Board of Purdue.

197. Ilene Sackler Lefcourt is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and the Purdue-related entities from the sale of opioids.

198. At all relevant times, Beverly Sackler served as a trustee of one or more trusts that beneficially own and control Purdue and the Purdue-related Additional Defendants and to which 50% of the profits of Purdue and the Purdue-related Additional Defendants from the sale of opioids has

been conveyed. She has also served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s. Beverly Sackler is the direct or indirect beneficiary of some portion of 50% of the profits earned by Purdue and the Purdue-related business entities from the sale of opioids.

199. Theresa Sackler is the direct or indirect beneficiary of 50% of the profits earned by Purdue and the Purdue-related Additional Defendants from the sale of opioids. She also has served as a member of the board of directors of Purdue and Purdue-related business entities since the 1990s.

200. David A. Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and the Purdue-related business entities from the sale of opioids. He has also served as a member of the board of directors of Purdue and Purdue-related entities since 2012.

201. The Sackler Family Defendants, the Sackler Families, and the Richard Sackler Trust, are the sole beneficial owners of Purdue and its associated companies and the Purdue-related business entities. All of Purdue's and its associated companies' profits go to family trusts and business entities dominated and controlled by Sackler Family Defendants.

202. Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, Rhodes Tech, Rhodes Tech Inc., Rhodes Pharma, Rhodes Pharma Inc., the Raymond Sackler Trust (through its trustees), and P.F. Labs each knowingly aided, abetted, participated in, and benefitted from the wrongdoing of Purdue as alleged in the Amended Complaint.

ii. The Sackler Families and the Development of OxyContin

203. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company ("PF Co.") in 1952.

204. PF Co. had been formed in 1892 by Dr. John Purdue Gray and George Frederick Bingham and incorporated in New York on June 29, 1911.

205. After Arthur's death, Mortimer and Raymond bought out his share. Since that time PF Co. and its associated companies have all been owned by the Raymond Sackler Family and the Mortimer Sackler Family.

206. PF Co. is no longer an active New York corporation, having been merged into PF Labs on May 7, 2004.

207. At all relevant times, PF Co. and PF Labs have been beneficially owned by the Sackler Families and controlled by them through Defendant Sackler Family members.

208. After the Sackler brothers acquired PF Co. in 1952, they sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur was not involved, on paper at least, in running the family business because that would have been a conflict of interest. Raymond became the head executive of the family's US business while Mortimer ran the UK side of the business.

209. Beginning in the 1980s PF Co. and its associated companies engaged in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling or distributing opioids throughout the United States.

210. In the 1980s, the Sackler Families, through a UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. PF Co. marketed this extended-release morphine as MS Contin. It quickly became the Sackler Families' best seller. As the patent expiration for MS Contin loomed, the Sackler Families searched for a drug to replace it. Around that time, Richard Sackler had become more involved in the management of the families' businesses. Richard had grand ambitions for the family business; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean really big." Richard believed Purdue should develop another use for its "Contin" timed-release system.

211. In 1990, Purdue's VP of clinical research, Robert Kaiko, sent a memo to Richard and

other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, the relatively weak oxycodone-acetaminophen combination pill, or Percodan, where it was blended with aspirin. By contrast, the oxycodone pill developed by Purdue – OxyContin -- was pure oxycodone in a time-release formula similar to MS Contin, and it was more potent than morphine. Purdue also decided to produce pills with as much as 160 milligrams of oxycodone, far in excess of any other prescription opioid.

212. OxyContin was created by PF Co., but responsibility for designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and distributing OxyContin and other opioid products was shared among PF Co., Purdue, PF Labs, and other Purdue-related companies.

213. At relevant times, OxyContin was manufactured by PF Labs.

214. MS Contin had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what is more, it was sometimes mistakenly called "oxycodeine," which also contributed to a false perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this false perception to its advantage when it eventually pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.

215. Even though oxycodone did not have the same stigma as morphine, in focus groups conducted before OxyContin's release, Purdue learned that doctors were concerned about the abuse potential of opioids. The focus group concluded that the perceived abuse potential of opioids was the

"'biggest negative' that might prevent widespread use of the drug." For Purdue and OxyContin to be "really big," Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

216. Despite the fact that there has been little or no change in the amount of pain reported in the U.S. over the last twenty years, Purdue recognized an enormous untapped market for its new drug. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."

iii. The Sacklers and the Integration of Advertising and Medicine

217. Before the defendants in this action began their marketing campaign for prescription opioids, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance. The commercial success of prescription opioids thus would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

218. As it turned out, Purdue was uniquely positioned to execute just such a maneuver, thanks to the legacy of Arthur Sackler, the (now-deceased) brother of Raymond and Mortimer Sackler.

219. 'Arthur Sackler created the pharmaceutical advertising industry as we know it—laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

220. Arthur Sackler, a psychiatrist turned "ad man," was both a psychiatrist and a marketing executive, and, by many accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at Creedmoor State Hospital in New York and the president of an advertising agency called William Douglas McAdams. Arthur pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical education courses. He understood the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.

221. Arthur Sackler revolutionized medical marketing in the 1950's and 60's by creating the very marketing ploys his family later used to perpetuate the massive fraud alleged in this action. In striving to make Pfizer (with its blockbuster drug, valium) a household name among physicians, Arthur Sackler recognized that "selling new drugs requires a seduction of not just the patient but the doctor who writes the prescription," and he maximized influence over physician prescribing by developing the following marketing ploys to disseminate pharmaceutical messaging to the masses under the guise of science and truth: a. contacting prescribers directly with a variety of perks, benefits and even job offers; b. publishing seemingly neutral articles in medical journals, citing scientific studies (frequently underwritten by the pharmaceutical companies whose products he was marketing); c. marketing illnesses (i.e., lamenting and marketing the under treatment of purported illnesses and the corresponding under-utilization of drugs he was promoting); d. paying prominent physicians to endorse his products; and e. funding continuing medical education programs ("CME's"), controlling the messaging of key opinion leaders, and maximizing influence over physician prescribing practices.

222. In the 1960s, Purdue made Valium into the first hundred-million dollar drug, so

popular it became known as "Mother's Little Helper." His expertise as a psychiatrist was one of the keys to his success. When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called "psychic tension"— essentially stress—and pitched Valium as the solution. The campaign, for which Arthur was compensated based on volume of pills sold, was a remarkable success.

223. In marketing tranquilizers Librium and Valium, Purdue broadened his customer base to potentially include everyone. For example, one campaign encouraged doctors to prescribe Valium to people with no psychiatric symptoms whatsoever, urging doctors to "consider the usefulness of Valium" in patients with no demonstrable pathology. Such marketing led one physician, writing in the journal Psychosomatics in 1965, to ask, "When do we not use this drug?"'

224. As the line between medical education and medical marketing became very deliberately blurred, Valium became the pharmaceutical industry's first hundred-million-dollar, and then billion-dollar, drug. For Arthur Sackler's efforts in designing and creating these wildly-successful medical marketing strategies, he was posthumously inducted into the Medical Advertising Hall of Fame, but as succinctly put by Allen Frances, the former chair of psychiatry at Duke University School of Medicine: '"Most of the questionable practices that propelled the pharmaceutical industry into the scourge it is today can be attributed to Arthur Sackler."'

225. In other precursors of the current crisis, Purdue promoted these drugs despite the lack of any studies of their addictive potential. Additionally, Arthur Sackler started his own newspaper, the Medical Tribune, despite concerns that a pharmaceutical advertiser should not be publishing a medical periodical directed at doctors. Purdue paid Key Opinion Leaders ("KOLs"), including for example, Henry Welch (then chief of FDA's antibiotics division), almost $300,000 in exchange for his help in promoting pharmaceutical drugs. By the 1970's, doctors were prescribing more than 100 million tranquilizer prescriptions annually, creating what Sen. Edward Kennedy called "a nightmare

of dependence and addiction."

iv. Purdue's Directors Knew About, and Participated in, Purdue's Wrongdoing

226. The members of the board of Purdue were intimately involved in the activities of the entities that they managed, often on a weekly or even daily basis.

227. Purdue, PF Co., PF Labs, and the Sackler Families launched OxyContin with one of the biggest pharmaceutical marketing campaigns in history, deploying many persuasive techniques pioneered by Arthur. They trained and armed a force of approximately 1,000 sales representatives with charts showing OxyContin's purported benefits. A major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or for cancer pain but also for less acute, longer-lasting pain, such as arthritis, back pain, sports injuries, fibromyalgia. The number of conditions that OxyContin could treat was, according to defendants, unlimited.

228. The training included "training in 'overcoming objections' from clinicians." "If a doctor inquired about addiction," the representative was instructed to respond thus: "'The delivery system is believed to reduce the abuse liability of the drug.'" Another sales representative said that Purdue executives "told us to say things like: "it is 'virtually' non-addicting."

229. Purdue sales representatives were provided with studies and literature provided by other physicians. Purdue had a speakers' bureau through which it paid several thousand doctors to attend medical conferences and deliver presentations about OxyContin's merits. "Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton." Internal documents reflect that doctors who attended these seminars wrote OxyContin prescriptions more than twice as often as those who didn't.

230. Purdue also advertised in medical journals and produced promotional videos featuring not just satisfied patients but also doctor's testimonials. "The marketing of OxyContin relied on an

empirical circularity: the company convinced doctors of the drug's safety with literature that had been produced by doctors who were paid, or funded, by the company." According to a former OxyContin sales representative, Richard Sackler was "'the dude that made it happen.'" Richard Sackler himself was tireless in his dedication to OxyContin's success. When benefit plans began citing OxyContin abuse as an excuse not to pay, Richard Sackler sent an email to sales representatives stating that, for insurers, "'addiction' may be a convenient way to just say 'NO.'"

231. Members of the Sackler family were daily on site at Purdue's headquarters, controlling the management of their family business and all of its employees.

232. Richard Sackler is named as inventor on some 50 patents relating to oxycodone and other pain medications, including several patents apparently issued as late as 2016. Virtually all such patents invented by Richard Sackler were assigned to Purdue.

233. In 1997, both Richard and Kathe Sackler were part of a conspiracy to deceive physicians into believing that oxycodone was half as strong as morphine, when in fact the opposite was true; this deception was known by Purdue to ease the fears of well-meaning and careful physicians about prescribing OxyContin for non-cancer pain uses.

234. In the late 1990s Richard, Jonathan and Kathe Sackler participated in an unlawful attempt to deceive European drug regulators into classifying OxyContin as totally uncontrolled, i.e., capable of being obtained without a prescription, despite the fact that all of these family members were by then well aware of the abuse liability of the drug in the U.S.

235. In 2001, Kathe Sackler attended a talk given by the chief medical officer of Sikorsky Aircraft, in which the speaker expressed grave concern about the risks associated with OxyContin; instead of acknowledging this fact to the medical officer, Kathe Sackler instead remained silent and returned to the Purdue headquarters, where employees were directed to find ways to undercut and deflect the Sikorsky medical officer's concerns.

236. In the period around 1999-2003, Purdue developed a method to cause company emails to self-destruct at a pre-determined time; this was an attempt to create a system where potentially incriminating documents would automatically self-destruct, even after receipt by unrelated third-parties. Richard, Jonathan and Kathe Sackler all were directly aware and supportive of this project.

v. Members of the Sackler Families Were Aware of Risks Associated with OxyContin No Later than the Summer of 1999

237. That prescription opioids would lead to addiction, and specifically that OxyContin could be, and was being, abused has been known to Purdue and to the members of the Sackler Families involved in running the family business since at least the summer of 1999.

238. In summer of 1999, a Purdue sales representative wrote to the President of Purdue reporting widespread abuse of OxyContin. As a result of that memo, a secretary at Purdue, Maureen Sara, was tasked with doing research on the Internet to learn about the nature and scope of the abuse, specifically to learn about how recreational drug users were misusing OxyContin.

239. In order to carry out her assignment, Ms. Sara began visiting drug-user Internet "news groups" or "chat rooms" on a daily basis. Two groups in particular that Ms. Sara visited were 'alt.drugs' and 'alt.drugs.hard'. For a period of time, from late-summer and early fall of 1999, Ms. Sara would forward screen shots from these news groups on a daily basis to Howard Udell, then General Counsel of Purdue.

240. In October or November, 1999, Ms. Sara prepared a memo summarizing her research into misuse of OxyContin. The memo described how users would remove the coating on the OxyContin pills, crush them, cook them, and snort or shoot them. Ms. Sara sent the memo containing the details of OxyContin abuse by drug users not only to the President of Purdue and to its General Counsel, but also to Purdue's then-medical director, and directly to members of the Sackler Families involved in the management of the company, including Richard Sackler, Jonathan Sackler, and Kathe

Sackler.

241. Purdue, Richard Sackler, Jonathan Sackler, and Kathe Sackler were thus all aware of the risk and abuse potential and reality of OxyContin long before Purdue acknowledged the same to government, the healthcare community or the public. In sworn testimony before the U.S. House of Representatives in 2001, Purdue President Michael Friedman, in the presence of Purdue General Counsel Howard R. Udell, swore that the first the companies knew of widespread abuse of OxyContin was in the year 2000. This was, of course, patently inconsistent with what the members of the Sackler Families knew from the Sara memo they had received in 1999. No member of the Sackler Families at any time tried to correct the false narrative promulgated far and wide about the abuse liability of OxyContin, nor corrected the false statement about when Purdue became aware of this problem with the drug.

242. Richard Sackler, Kathe Sackler, Jonathan Sackler, Theresa Sackler, Mortimer D.A. Sackler and Ilene Sackler have, individually or in combination, been aware since at least 1999 of potential liability for Purdue, and those acting in concert with Purdue, because of the addictive nature of OxyContin. With the intention of shielding from creditors the proceeds of their wrongdoing, they have stripped out of Purdue and the Purdue-related Additional Defendants each and every year hundreds of millions of dollars of profits from the sales of OxyContin and other opioid-containing medications, including a generic form of OxyContin sold by Rhodes Pharma. All such transfers were and are fraudulent within the meaning of applicable fraudulent transfer statutes and case law; all such transfers unjustly enriched the recipients; and all such transferred funds should be clawed back from the Sackler Defendants (i.e., the "Trust For the Benefit of Members of the Raymond Sackler Family", the "Sackler Family Defendants" and "Sackler Families") as well as from all other named individual defendants that had served as officers or board members of the following defendants: the Purdue Entities, Rhodes Technologies, Rhodes Technologies Inc., Rhodes Pharmaceuticals L.P., Rhodes

Pharmaceuticals Inc., and P.F. Laboratories, Inc., as well as the recipient of 50% of the profits from the sale of opioids by Purdue and Purdue Entities, Rhodes Technologies, Rhodes Technologies Inc., Rhodes Pharmaceuticals L.P. , Rhodes Pharmaceuticals Inc. and P.F. Laboratories, Inc.in order to satisfy the opioid-related liabilities of the companies from which they were transferred.

vi. Purdue-Related Business Entities Continued to Oversee Purdue's Wrongdoing Even after Purdue Was Fined and Warned about Its Conduct

243. From 2001 to 2007, Purdue was investigated by 26 states and the U.S. Department of Justice. Beginning in or about 2003, advised by Stuart Baker, who served as legal counsel to the entire Purdue organization and the Sackler Families, all of the Sacklers who served as executive officers of Purdue resigned out of concern that they might be held personally liable for conduct on behalf of Purdue in which they had previously engaged and in which they expected and intended to continue to engage after their respective resignations.

244. In 2007, PFC agreed to pay nearly $700 million and pleaded guilty to a felony for misleading doctors and patients about opioids. Purdue admitted that its supervisors and employees, "with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." At the same time, Purdue executive officers Michael Friedman (the CEO), Howard Udell (Vice President and General Counsel), and Paul Goldenheim (Chief Medical Officer) pleaded guilty to criminal charges that they let Purdue deceive doctors and patients about its opioids.

245. As part of the plea agreement in 2007, Purdue agreed to a detailed Corporate Integrity Agreement with the U.S. government. The Agreement required Purdue to appoint a Compliance Officer who would "be a member of senior management of Purdue," "make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors," and "be authorized to report on such matters to the Board of Directors at any time." The Corporate Integrity

Agreement was built on the idea that the directors would ensure that Purdue never deceived doctors and patients again.

246. The Corporate Integrity Agreement included the directors as "Covered Persons" from 2007 through 2012. All Covered Persons, including the directors and CEO, were required to comply with rules that prohibit deception about Purdue opioids. The directors were required to undergo hours of training to ensure that they understood the rules. The directors were required to report all violations of the rules. The directors were warned that they could face consequences if they failed to comply with the rules. The directors certified that they had read and understood the rules and would comply with them.

247. The directors were acutely aware of their obligations under the Corporate Integrity Agreement because, in 2009, Purdue had to report to the Inspector General of the U.S. Department of Health and Human Services that it had not immediately trained a new director on the Agreement. Purdue reported: "a new Director was appointed to Purdue's Board of Directors, without timely notice to either Corporate Compliance or the Office of General Counsel, as otherwise required by policy, resulting in failure to timely launch the training assignment to this new Board member." Purdue assured the U.S. government that it had trained the new director: "Relevant personnel were reminded of existing policy to notify Corporate Compliance and the Office of General Counsel of changes to the Board of Directors. In both instances, these individuals completed their training assignments within 1 day of Corporate Compliance learning of this issue." Purdue promised the government that the director's training had addressed "the proper methods of promoting, marketing, selling, and disseminating information about Purdue's products," so Purdue would never deceive doctors and patients again.

248. Every year since the 2007 guilty plea and Corporate Integrity Agreement, Purdue's directors received warning signs about Purdue's ongoing misconduct and opportunities to stop it.

249. In 2008, more Americans died from opioid overdoses than ever before.

250. In 2009, the American Journal of Public Health published an article about Purdue's opioid marketing entitled, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy." The article detailed Purdue's use of sales representatives, targeting of high-prescribers, and deception about addiction. That same year, CDC reported that deaths from opioids had recently tripled. In 2010, Time magazine published a story about Purdue's opioids entitled, "The New Drug Crisis: Addiction by Prescription." Overdoses were the leading cause of accidental death in 15 states. By the spring of 2010, Purdue's directors had been told that Purdue could not get product liability insurance to cover OxyContin.

251. In 2011, the White House announced that prescription drug abuse was the nation's fastest-growing drug problem and called for "educating healthcare providers about prescription drug abuse … so they will not over-prescribe[.]" The CDC announced that prescription opioid overdoses had reached epidemic levels and called out Purdue's opioids by name. That same year, Fortune magazine interviewed Purdue executives, including Vice President Alan Must. Fortune published a story about Purdue, the Sackler Families, and evidence that they profited from opioid addiction. Mr. Must admitted that Purdue was "well aware" of concerns about its conduct: "We are well aware of detractors. For those individuals who think we're evil … I don't think there's anything we can do that is going to change their opinion."

252. In 2012, the U.S. Senate launched an investigation into whether Purdue was deceiving doctors and patients about opioids. In a letter to the CEO of Purdue, the Senators warned of "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers." The Senate letter warned Purdue specifically of the danger of patients taking higher doses: "over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks while data suggest

that hundreds of thousands of patients nationwide may be on potentially dangerous doses." The Senate letter also warned about Purdue misleading doctors and patients: "There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness." The Senate put the directors on notice that they were under scrutiny, demanding that Purdue produce to investigators a set of "presentations, reports, and communications to Purdue's management team or board of directors from 2007 to the present."

253. In 2013, the Los Angeles Times revealed that Purdue had been compiling a list for the past decade of 1,800 doctors suspected of recklessly prescribing its opioids, but Purdue had reported only 8% of them to authorities. Purdue attorney Robin Abrams gave multiple interviews to the newspaper. Abrams was a Vice President of Purdue, and she signed Purdue's 2007 settlement agreement. In 2013, she admitted that Purdue had the list, and said Purdue would not agree to disclose it to authorities because, "I don't really want to open up an opportunity for folks come in here and start looking and second-guessing."

254. Abrams and Purdue's directors knew they had reason to fear scrutiny. The state of Kentucky was prosecuting a lawsuit against Purdue for deceiving doctors and patients about opioids. Purdue's lawyers surveyed residents who could be on the jury. One-third knew someone who overdosed or was seriously hurt taking a Purdue opioid, and 29 percent knew someone who died. Purdue itself filed those statistics in court.

255. In 2014, Edward Mahony, the Executive Vice President, CFO, and Treasurer of Purdue stated that the Kentucky lawsuit was so significant that it could jeopardize "Purdue's long-term viability." That same year, the Governor of Massachusetts declared the opioid crisis a public health emergency.

256. In 2016, the CDC published the CDC Guideline for Prescribing Opioids for Chronic

Pain to try to stop dangerous opioid prescribing.

257. In 2017, the President of the United States declared the opioid crisis a national public health emergency.

258. PPI's directors, including Sackler Family Defendants, either knew or should have known about these warnings and many others.

259. The Sackler Family Defendants oversaw Purdue's scheme to send sales representatives to visit doctors thousands of times. They oversaw Purdue's scheme to hire top prescribers to promote its opioids. They oversaw Purdue's effort to get more patients on higher doses of opioids for longer periods. They were aware of, allowed and directed the content of the messages conveyed in Purdue's marketing.

260. The quarterly reports distributed to the directors of PPI demonstrate that the directors in fact controlled both PPI and PPLP and, upon information and belief, PPPI and PPTI. The reports and minutes make clear that the directors of PPI were kept fully informed of the activities of Purdue in the areas "Finance," "Sales & Marketing," "Manufacturing & Supply Chain," "Quality," "Research & Development," "Discovery Research," "Licensing & Business Development," "Corporate Compliance," "External Affairs," "Health Policy," "Human Resources," and "Information Technology" — all of which were overseen by the directors.

261. Richard Sackler testified that the sales representatives were the main way that Purdue promoted its opioids. He testified that the key to getting doctors to prescribe and keep prescribing Purdue opioids was regular visits from the sales force. The board tracked the exact number of sales representatives and the exact number of visits they made to urge doctors to prescribe Purdue opioids. The board knew which drugs were promoted; how many visits sales representatives averaged per workday; how much each visit cost Purdue; and the company's plan for sales visits in each upcoming quarter. The Board approved specific plans to hire new sales representatives, hire and promote new

District and Regional managers, and create sales "territories" in which representatives would target doctors.

262. The directors, which included Sackler Family Defendants, oversaw the tactics that sales representatives used to push opioids. A board report analyzed a Purdue initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor to "16.7 minutes in front of the customer.

263. The directors, which included Sackler Family Defendants, oversaw promotional claims that representatives presented to doctors during sales visits. They received reports, for example, that a "review of call notes" recorded by Purdue sales representatives "suggested potential comparative claims of superiority of Purdue products relative to competitors," and deceptive promotion of opioids as treatment for "minor pain," including hundreds of examples of deceptive marketing that required "extensive remedial actions." The directors oversaw Purdue's research, including research that contradicted its marketing. The board received reports about studies of Purdue opioids in "opioid-naïve" patients and patients with osteoarthritis, down to the details of the strategy behind the studies and the enrollment of the first patients.

264. The directors, which included Sackler Family Defendants, oversaw Purdue's improper response to signs of "abuse and diversion" by high-prescribing doctors. The board was told exactly how many "Reports Of Concern" Purdue sales representatives submitted to the company about doctors they had visited to promote opioids (572 Reports Of Concern in the July 2007 board report); how many "field inquiries" Purdue had decided to conduct in response to the reports (21 inquiries in response to 572 Reports Of Concern); and even that six Reports Of Concern were submitted in Massachusetts.

265. The directors, which included Sackler Family Defendants, even monitored sales representatives' emails. Purdue held thousands of face-to-face sales meetings with doctors, but the

company prohibited its sales representatives from writing emails to doctors, which could create evidence of Purdue's misconduct. When Purdue found that some sales representatives had emailed doctors, the company conducted an "investigation" and reported to the board that sales representatives had been disciplined and that their emails would be discussed at the board meeting.

266. The directors, which included Sackler Family Defendants, also oversaw Purdue's strategy to pay high prescribers to promote Purdue opioids. A report for the board listed the exact number of conferences and dinner meetings, with attendance figures, and assured the directors: "We are tracking the prescribing trends of these attendees following the programs and will report the results in future reports." The board was told the amounts paid to certain doctors, and they received detailed reports on the Return on Investment that Purdue gained from paying doctors to promote its drugs. The board was told that Purdue would allow a "spending limit for gifts" of $750 per doctor per year; and that the directors should personally report when they gave money, meals, or gifts to doctors to promote Purdue drugs. The board was told explicitly that paying doctors to promote opioids was "a high-risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities." When Congress required disclosure of drug company payments to doctors, the board was told there were "significant compliance implications" for Purdue.

267. The directors, which included Sackler Family Defendants, also oversaw Purdue's strategy to push patients to higher doses of opioids — which are more dangerous, more addictive, and more profitable. The board routinely received reports on Purdue's effort to push patients to higher doses. A report alerted the board that "Net sales of the 40 and 80 mg strengths of OxyContin" had fallen below Purdue's targets in the fall of 2010 and were $85 million below budget. By summer, the board learned that income was $500 million below budget "mainly due to declining sales in 40 mg and 80 mg strengths. By fall, the board reviewed an assessment that Purdue had lost more than $800 million in revenue because patients weren't taking enough 40 mg and 80 mg doses. The board dug

into the issue. Multiple reports to the board identified as a "threat" an initiative by public health authorities to save lives by requiring doctors to consult with pain specialists before prescribing opioid doses higher than 80mg/day. The CEO and directors oversaw Purdue's effort to push back against that public health "threat." Executives were pleased to report to the directors in 2013 that "initiatives to validate increased total daily doses are having impact in the field."

268. The directors, which included Sackler Family Defendants, also oversaw Purdue's scheme to use higher doses of opioids to keep patients on drugs for longer periods of time. The board received detailed reports of how many patients stayed on Purdue's opioids for long periods (for example, longer than 35 days), along with Purdue's internal research showing that getting patients on higher doses keeps them on the drugs longer — all of which puts patients at greater risk of addiction and death. The board received the confidential results of a study of 57,000 patients that Purdue performed explicitly to determine how opioid dose "influences patient length of therapy." The results showed that patients on the highest doses "are the most persistent." The "Recommended Actions" presented to the board included "additional workshops for the sales force" and "specific direction" to the sales representatives about using higher doses to keep patients on drugs longer.

269. The board, which included Sackler Family Defendants, was told in writing that encouraging higher doses "is a focal point of our promotion," and that sales representatives would "emphasize the importance" of increasing patients' opioid doses, as soon as 3 days after starting treatment. The board even tracked specific sales materials, such as "two new patient profiles designed to improve patient identification and titration" – to get more opioid-naïve and elderly patients on higher doses of opioids for longer periods of time. The board was told the exact research behind the sales strategy: higher doses would keep patients on drugs longer because Purdue had found that "83% of patients who discontinued were never titrated to higher doses." The directors knew or should have known that Purdue's sales strategy was deceptive and that putting patients on opioids at higher doses

and for longer periods increased the risk of addiction, overdose, and death.

270. The directors, which included Sackler Family Defendants, also oversaw Purdue's strategy of using "savings cards" to get patients on Purdue opioids for longer periods. The board knew how many thousands of cards were used each quarter, how the company calculated the Return On Investment, and that the explicit goal of the program was to hook patients to "remain on therapy longer."

271. The directors, which included Sackler Family Defendants, also oversaw Purdue's strategy to target prescribers who did not have special training in opioids (primary care doctors, nurse practitioners, and physician assistants) because they "show the highest responsiveness" to Purdue's sales push. Purdue continued that strategy even though the DEA had expressed concern that Purdue was promoting opioids to clinicians who were not adequately trained in pain management. The directors also oversaw Purdue's strategy to target elderly patients by promotion "targeted to HCPs that practice in the long-term care setting," even down to the details of advertising that "leverages images of older patients." The directors knew or should have known that Purdue's sales strategy was deceptive and that targeting primary care doctors and elderly patients increased the risk of addiction, overdose, and death.

272. The directors, which included Sackler Family Defendants, also oversaw Purdue's push to steer patients away from safer alternatives. They tracked the company's effort to emphasize "the true risk and cost consequence of acetaminophen-related liver toxicity." The board even oversaw Purdue's deceptive websites and received reports about the specific section that was found to be deceptive by the New York Attorney General.

273. The directors, which included Sackler Family Defendants, also oversaw Purdue's response to signs that patients were being harmed. Reports of harm came in by the hundreds and even thousands. One board report explained that "in excess of 5,000 cases with alleged adverse events

have already been received and processed by Drug Safety and the Litigation Support group" during a single quarter.

274. Each of the reports described above was, upon information and belief, sent to the attention of the Sackler family members on the Purdue's board at the time they were prepared.

275. Opioid-related cases of NAS are rising at such a rapid pace that cities, counties and health care systems are unable to keep up logistically.

DISTRIBUTOR DEFENDANTS' WRONGFUL CONDUCT

276. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including Defendants Cardinal, McKesson, and AmerisourceBergen, which together account for 85-90 % of all revenues from drug distribution in the United States, an estimated $378.4 billion in 2015. The distributors then supply opioids to pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

277. Manufacturer Defendants and Distributor Defendants share the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain.

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

279. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

280. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

281. Every year, thousands of people in Oklahoma misuse and abuse opioid pain relievers that can lead to addiction, neonatal abstinence syndrome, overdose and death.

282. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged as a public health crisis in the United States.

283. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use. Another study revealed that 75% of those who began their opioid abuse in the 2000s started with prescription opioid. The CDC has reported that people who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin.

284. Plaintiffs and the Class have been significantly damaged by the effects of the Distributor Defendants' opioid diversion.

285. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

286. In addition to having common law duties, the Distributor Defendants are governed

by the statutory requirements of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*. and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants' violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. The Distributor Defendants' repeated, unabashed, and prolific violations of these requirements show that they have acted in total reckless disregard.

287. By violating the CSA, the Distributor Defendants are also liable under the law of Oklahoma as herein alleged.

288. The CSA creates a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

289. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

290. All opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

291. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors' controlled substances, acquisition transactions, and distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

292. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. 21 U.S.C. § 827(d) (l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

293. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.2l(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

294. To maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels.

When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR § 1301.71.

295. For years the Distributor Defendants have known of the problems and consequences of opioid diversion in the supply chain, and have committed repeated violations of the laws and regulations of the United States as cited above consequently making them liable under Oklahoma law.

296. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the "red flags" distributors should look for to identify potential diversion.

297. Since 2007, the DEA has hosted no less than five conferences to provide opioid distributors with updated information about diversion trends. The Defendant Distributors attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance

documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

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

299. The September 27, 2006 letter reminded registrants that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious.

300. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances

would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

301. The Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances.

302. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

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

304. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity" (emphasis added).

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

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

307. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have miserably and negligently failed.

308. The Distributors Defendants have knowingly or negligently allowed diversion. Their wrongful conduct and inaction have resulted in numerous civil fines and other penalties recovered by state and federal agencies- including actions by the DEA related to violations of the Controlled Substances Act.

309. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

310. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the

middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

311. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

312. Relying upon state laws and regulation, various state boards of pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations.

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

314. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable risk of damage to Plaintiffs and the Class.

315. The Distributor Defendants have supplied massive quantities of prescription opioids in Oklahoma with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

316. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to flow into Oklahoma was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

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

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

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

320. It was reasonably foreseeable to the Distributor Defendants that their conduct in

flooding the consumer market of Oklahoma with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

321. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including neo-natal addiction and NAS.

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

323. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed to patients and citizens of Oklahoma were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third-parties, Plaintiffs and the Class.

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

325. If any of the Distributor Defendants adhered to effective controls to guard against diversion, the Class would have avoided significant damages.

326. The Distributor Defendants made substantial profits over the years based on the diversion of opioids affecting Oklahoma. Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiffs and the Class. The Distributor Defendants knew full well that Plaintiffs and the Class would be unjustly forced to bear these injuries and damages.

327. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for Plaintiffs and the

Class. Their conduct poses a continuing economic threat to the communities that must deal with ongoing needs of children afflicted with NAS.

CVS

328. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. CVS also operates retail stores, including in Oklahoma, that sell prescription medicines, including opioids.

329. At all times relevant to this Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Oklahoma.

330. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations.

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

332. As recently as July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

333. This fine was preceded by numerous others throughout the country.

334. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

335. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

336. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

337. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

338. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

339. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

340. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had

expired.

341. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

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

343. CVS has had knowledge and/or notice of the opioid problem since at least 2002.

344. At any time since CVS had knowledge and/or notice of the opioid problem it could have unilaterally taken steps to curtail and prevent expansion of the problem, but it failed to do so.

345. In their capacity as wholesale distributors, CVS and its subsidiaries are "Distributor Defendants" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against CVS.

Rite Aid

346. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite-Aid also operates retail stores, including in Oklahoma, that sell prescription medicines, including opioids.

347. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Oklahoma.

348. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the third-largest drug store chain in the United States, with annual revenue of more than $21 billion.

349. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.

350. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R1301.76(b).

351. In their capacity as wholesale distributors, Rite-Aid and its subsidiaries are "Distributor Defendants" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Rite Aid.

Walgreens

352. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Oklahoma.

353. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

354. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription opioids to be diverted for abuse and illegal black market sales.

355. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

356. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

357. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.

358. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

359. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

360. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid

use of some Medicaid patients who were considered high-risk.

361. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

362. In their capacity as wholesale distributors, Walgreens and its subsidiaries are "Distributor Defendants" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Walgreens.

Wal-Mart

363. Walmart, through its various DEA registered affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States.

364. In its capacity as a wholesale distributor, Wal-Mart is a "Distributor Defendant" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Wal-Mart.

Miami-Luken

365. During all relevant times, upon information and belief, Miami-Luken has distributed substantial amounts of prescription opioids to providers and retailers in Oklahoma.

366. On November 23, 2015, the DEA issued an Order to Show Cause to begin the process of revoking Miami-Luken's Certificate of DEA Registration.

367. In its revocation proceeding, the DEA has alleged that Miami-Luken failed to maintain effective controls against diversion of controlled substances and that the company failed to operate a system to disclose suspicious orders of controlled substances when it shipped controlled substances,

particularly oxycodone and hydrocodone, to customers in southern Ohio, eastern Kentucky, and southern West Virginia.

368. In early 2016, Miami-Luken agreed to pay the state of West Virginia $2.5 million to resolve allegations that the company knowingly shipped opioids to West Virginia pharmacies without exercising sufficient monitoring or control.

369. In its capacity as a wholesale distributor, Miami-Luken is a "Distributor Defendant" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Miami-Luken.

CostCo

370. Costco failed to track and report suspicious sales of its opioid drugs.

371. Costco is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

372. Contrary to its duties as a registrant, in 2017, Costco Wholesale was fined $11.75 million as a result of a multijurisdictional investigation by the DOJ relating to CSA violations.

373. According to the investigation, Costco pharmacies filled prescriptions that were incomplete, lacked valid DEA registration numbers or were for substances beyond various doctors' scope of practice. Additionally, the settlement resolves allegations that Costco failed to keep and maintain accurate records for controlled substances at its pharmacies.

374. Between January 1, 2012 and December 31, 2015, certain Costco pharmacies dispensed controlled substances inconsistent with their compliance obligations under the CSA and its implementing regulations. The violations include: filling prescriptions from practitioners who did not have a valid DEA number, incorrectly recording the practitioner's DEA number, filling prescriptions outside the scope of a practitioner's DEA registration, filling Prescriptions that

did not contain all the required information, failing to maintain accurate dispensing records, and failing to maintain records for their central fill locations in Sacramento, California and Everett, Washington.

375. According to U.S. Attorney Eileen M. Decker: "These are not just administrative or paperwork violations – Costco's failure to have proper controls in place in its pharmacies played a role in prescription drugs reaching the black market…."

376. Furthermore, Costco could and should have taken action that: (a) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate- release formulations of opioids before extended-release opioids are dispensed.

377. Having knowledge and/or notice of the damages that Costco's conduct had caused to Plaintiff and the Class, Costco failed to take other steps to help curb the damages already incurred by Plaintiff due to Defendants, including Costco, could have: (a) donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) run public education campaigns in which Costco ran public education programs; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and h) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

378. Costco could have and should have implemented these measures at any point in the last 15 years.

379. And the failure to take such steps that Costco should have taken was negligent and did result in significant damages to Plaintiff and the Class.

380. In its capacity as a wholesale distributor, CostCo is a "Distributor Defendant" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against CostCo.

Kroger

381. Kroger operates 2,268 pharmacies in the United States which distributed prescription opioids throughout the United States, including in Nebraska and Douglas County specifically.

382. At all relevant times, Kroger distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. Kroger universally failed to comply with federal and/or state law. Kroger engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges the unlawful conduct by Kroger is a substantial cause for the Opioid Crisis and the injuries to the Class.

383. In its capacity as a wholesale distributor, Kroger is a "Distributor Defendant" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Kroger.

H.D. Smith

384. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic, and specialty pharmaceuticals. At all times relevant to this Complaint, H. D. Smith distributed prescription opioids throughout the United States.

385. H. D. Smith has also routinely been found to have violated its duties to report

suspicious orders and halt suspicious shipments of prescription opioids. According to a recent letter from the U.S. House of Representatives Committee on Energy and Commerce, data provided to the Committee showed that between 2007 and 2008, H. D. Smith provided two pharmacies in Williamson, WV, a town with a population of 3,191, combined total of nearly 5 million hydrocodone and oxycodone pills - approximately 1,565 hydrocodone and oxycodone pills for every man, woman, and child in Williamson, WV.188 According to press reports, H. D. Smith distributed approximately 13.7 million hydrocodone and 4.4 million oxycodone pills to West Virginia between 2007 and 2012.189 Press accounts further indicate that H. D. Smith did not submit any suspicious order reports to the state for at least a decade.190 Upon information and belief, H. D. Smith engaged in similar wrongful activities in Oklahoma.

386. In its capacity as a wholesale distributor, H.D. Smith is a "Distributor Defendant" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against H.D. Smith.

Anda

387. Through its various DEA registrant subsidiaries and affiliated entities, Anda is the fourth largest distributor of generic pharmaceuticals in the United States. In October 2016, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") acquired Anda for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Oklahoma.

388. In its capacity as a wholesale distributor, Anda is a "Distributor Defendant" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Anda.

Discovery Rule and Tolling

389. The Defendants' unfair and deceptive conduct was well concealed, and only recently uncovered through exhaustive investigation and research. The defendants deliberately conducted much of their deception through in-person sales visits, in order to avoid generating a potentially discoverable paper trail of their misconduct. In the case of defendant Purdue, it is alleged to have prohibited its sales reps from emailing doctors regarding its opioids. The defendants also concealed from the general public their internal communications about their deceptive course of conduct, including their plans to hook more patients on higher doses for longer periods and, separately, their knowledge of inappropriate prescribing by high-prescribing doctors that they had targeted to prescribe their opioids.

390. Discovering the nature and extent of the defendants' unfair and deceptive conduct has been a time-consuming and complex process, further strained by defendants' lack of cooperation and baseless denials. Due to Defendants' deception, any statutes of limitation otherwise applicable to any claims asserted herein against all defendants have been tolled by the discovery rule and rules regarding fraudulent concealment.

CLASS ACTION ALLEGATIONS

391. Plaintiffs seek to represent the following class of individuals:

All Oklahoma persons under the age of eighteen who were diagnosed with neonatal abstinence syndrome (NAS) and whose birth mother (1) used opioids during gestation and (2) had a medical prescription for opioids before or during the gestation period.

392. Additionally, Plaintiffs bring this action on behalf of a subclass of Baby J.W.L.B. and all other similarly situated Oklahoma minors who have suffered personal injury damages from opioid exposure in utero, defined as follows:

All Oklahoma persons under the age of eighteen who were diagnosed with neonatal abstinence syndrome (NAS)

and whose birth mother (1) used opioids during gestation and (2) had a medical prescription for opioids before or during the gestation period, who have suffered personal injury damages from opioid exposure in utero.

393. Excluded from the Class are children of the Defendants and their officers, directors, and employees, as well as the Court and its personnel.

394. Plaintiffs and all others similarly situated are entitled to have this case maintained as a class action pursuant to Federal Rules of Civil Procedure for the following reasons:

395. The prerequisites for a class action under Federal Rule of Civil Procedure 23(a) are met.

a. The class is so numerous that joinder of all persons is impracticable. Although the precise number of children in the Class is currently unknown, Plaintiffs believe that the putative class is in the thousands, if not more.

b. There are common issues of law and fact, particularly whether Defendants' and their agents' policies and procedures that encouraged the continued use and abuse of opioids despite knowing the dangers caused harm to the Class.

c. Plaintiffs' claims are typical of the class. Plaintiffs' injuries are typical of the experience of the Class Members, having suffered personal injury and increased health risks necessitating medical monitoring and future medical treatment that are typical of the experience of the Class Members. Plaintiffs' interests are identical to and aligned with those of other Class Members. Plaintiffs and the Class Members have suffered an array of damages all stemming from the common trunk of facts and issues related to exposure to Defendants' manufacture and distribution of opioids.

d. Plaintiffs will fairly and adequately represent and protect the interests of the class because:

i. Plaintiffs have retained counsel experienced in the prosecution of class action litigation who will adequately represent the interests of the class;

ii. Plaintiffs and counsel are aware of no conflicts of interest between Plaintiffs and absent Class Members or otherwise that cannot be managed through the implementation of available procedures;

iii. Plaintiffs have, or can acquire, adequate financial resources to assure that the interests of the class will be protected; and

iv. Plaintiffs are knowledgeable concerning the subject matter of this action and will assist counsel in the prosecution of this litigation.

396. Further, any denial of liability and defenses raised by the Defendants would be applicable to all claims presented by all members of the class or can otherwise be managed through available procedures.

397. Defendants' conduct presents predominant common factual questions. This class is bound together by the common factual questions relating to whether the Defendants' tortious activities led to physicians over-subscription of opioids and created a diversionary market for opioids thus certification is proper under Rule 23 (b)(3). Regardless of whether Plaintiffs and the Class Members are presenting individualized damages such as pain & suffering, they will present common liability proof that is the same for each member of the Class. Across claim categories, Plaintiffs' common proof of Defendants' liability will involve the same cast of characters, events, discovery, documents, fact witnesses, and experts.

398. The need for proof of Plaintiffs' and Class Members' damages will not cause individual issues to predominate over common questions. The amounts of economic and non-economic losses can be efficiently demonstrated either at trial or as part of routine claims administration through accepted and court-approved methodologies set forth in the Federal Manual for Complex Litigation with the assistance of court-appointed personnel, including Special Masters. Certain types or elements of damage explained below as appropriate under Federal Rule of Civil Procedure 23(b)(3) are subject

to proof using aggregate damage methodologies or simply rote calculation and summation on a class-wide basis while individual damages may be determined via the mechanisms explained above.

399. A class action is superior to maintenance of these claims on a claim-by-claim basis when all actions arise out of the same circumstances and course of conduct. A class action allows the Court to process all rightful claims in one proceeding. Class litigation is manageable considering the opportunity to afford reasonable notice of significant phases of the litigation to Class Members and permit distribution of any recovery. The prosecution of separate actions by individual Class Members, or the individual joinder of all Class Members in this action, is impracticable and would create a massive and unnecessary burden on the resources of the courts and could result in inconsistent adjudications, while a single class action can determine, with judicial economy, the rights of each member of the class or subclasses, should that be determined to be appropriate.

400. The conduct of this action as a class action conserves the resources of the parties and the court system, protects the rights of each member of the class, and meets all due process requirements.

401. Certification of the Class with respect to particular common factual and legal issues concerning liability and comparative fault, as well as the necessary and appropriate quantum of punitive damages, or ratio of punitive damages to actual harm, is appropriate under Federal Rule of Civil Procedure 23(c)(4).

402. The particular common issues of liability, comparative fault, and the quantum of punitive damages or ratio of punitive damages to actual harm, are common to all Class Members no matter what type of harm or injury was suffered by each Class Member.

403. A class action may be maintained under Federal Rule of Civil Procedure 23(b)(2) because Defendants have acted or refused to act on grounds that apply generally to the Class, thereby making appropriate the entry of equitable and/or injunctive relief, including a medical monitoring

protocol and treatment programs, and injunctive relief to prevent recurrence of the conduct in the future.

404. As a result of Defendants' negligent conduct, the Rule 23(b)(2) Class Members are at increased risk of NAS and developmental issues. Early detection of neonatal exposure and developmental issues through examination and testing, with treatment as necessary, has significant value for Rule 23(b)(2) Class Members because such detection will help Class Members monitor, minimize and treat the harm therefrom. Due to neonatal opioid exposure by the Rule 23(b)(2) Class Members, surveillance in the form of periodic medical examinations and treatment is reasonable and necessary, because such surveillance will provide early detection, diagnosis and treatment of NAS and its effects. As a remedy for the negligent and unconscionable conduct alleged in this Complaint, Defendants should be required to fund a medical monitoring and treatment program designed to identify and combat NAS and its effects on the Class and provide desperately needed neonatal care and treatment programs as NAS affected children develop.

405. The particular common issues of liability, comparative fault, and the quantum of punitive damages or ratio of punitive damages to actual harm, are common to all Class Members no matter what type of harm or injury was suffered by each Class Member.

CAUSES OF ACTION

COUNT I – NUISANCE

406. Plaintiffs reassert the allegations of the foregoing paragraphs as if set forth fully herein.

407. The nuisance is the over-saturation of opioids in Oklahoma for non-medical purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use, including the increasing incidence of NAS.

408. All Defendants substantially participated in nuisance-causing activities.

409. Defendants' nuisance-causing activities include selling or facilitating the excessive sale of prescription opioids to the patients and citizens of Oklahoma, as well as to unintended users, including newborns and children, pregnant women, and potential mothers.

410. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

411. Defendants' activities unreasonably interfere with the rights of Plaintiffs and the Class.

412. The Defendants' interference with these rights of Plaintiffs and the Class is unreasonable because it:

a. Has harmed and will continue to harm the children and public health services of Oklahoma;

b. Is proscribed by statutes and regulation, including the CSA and the consumer protection statute;

c. Is of a continuing nature and it has produced long-lasting effects; and

d. Defendants have reason to know their conduct has a significant effect upon Plaintiff and the Class.

413. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities.

414. The resources of the communities of the Plaintiffs and the Class are insufficient to deal with needs created by the Opioid Crisis, and these limited resources are being unreasonably consumed in efforts to address the Crisis, including efforts to address the overwhelming number of children born with NAS.

415. Defendants' nuisance-causing activities are not outweighed by the utility of

Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Manufacturer Defendants dissemination of false "scientific" facts and advice.

416. At all times, all Defendants possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacy locations or other points of sale. Pharmaceutical Defendants flooded the distribution channels and the geographic and demographic area of Oklahoma with opioid pills. Distributor Defendants had the power to shut off the supply of illicit opioids to patients and consumers of Oklahoma, yet they did the opposite by flooding the U.S. (including Oklahoma) with opioid pills.

417. As a direct and proximate result of the nuisance, the communities of Plaintiffs and the Class have born a great burden trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services, counseling, healthcare, and child services.

418. Plaintiff Baby J.W.L.B. and the Class also have suffered unique harms different from the public at large, namely, that they personally suffer NAS.

419. The effects of the nuisance can be abated, and the further occurrence of such harm can be prevented. All Defendants share in the responsibility for doing so.

420. Defendants should be required to pay the expenses Plaintiffs and the Class and their communities have incurred or will incur in the future to fully abate the nuisance.

COUNT II - NEGLIGENCE AND GROSS NEGLIGENCE

421. Plaintiffs reassert the allegations of the foregoing paragraphs as if set forth fully herein.

422. Defendants owe a non-delegable duty to Plaintiff Baby J.W.L.B. and the Class to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the

light of the apparent risks.

423. There is no social value to Defendants' challenged behavior. In fact, Defendants' entire conduct, behavior, actions, misrepresentations, conspiracies, and omissions are against the law.

424. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of Baby J.W.L.B. and the Class.

425. Defendants' behavior caused a substantial injury and damage to Baby J.W.L.B. and the Class.

426. Defendants' conduct fell below the reasonable standard of care and was negligent. Their negligent acts include:

a. Consciously supplying the market in Oklahoma with highly-addictive prescription opioids, including misrepresenting, understating, or obfuscating the highly addictive propensities of opioid pills;

b. Using unsafe marketing, labeling, distribution, and dispensing practices, including failing to warn or advise physicians to conduct an addiction family history of each and every potential patient;

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

d. Failing to properly train or investigate their employees;

e. Failing to properly review and analyze prescription orders and data for red flags;

f. Failing to report suspicious orders or refuse to fill them;

g. Failing to provide effective controls and procedures to detect and/or guard against theft and diversion of controlled substances;

h. Failing to police the integrity of their supply chains; and

i. Creating misleading information with the intention of having prescribing physicians rely upon it.

427. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

428. Each Defendant sold prescription opioids in the supply chain knowing (a) there was a substantial likelihood many of the sales were for non-medical purposes and, (b) opioids are an inherently dangerous product when used for non-medical purposes, and (c) that every patient, before being prescribed even one opioid pill, needed to have a complete family history of addiction to alcohol and drugs, with any such history as a contraindication of any opioid use.

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

430. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

431. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, *e.g.*, the foreseeable conduct of: corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

432. Defendants are in a limited class of registrants authorized to legally distribute controlled substances. This places Defendants in a position of great trust and responsibility vis-a-vis Plaintiffs and the Class. Defendants owe a special duty to Plaintiffs, Baby J.W.L.B. and the Class. That duty cannot be delegated to another party.

433. Plaintiffs, Baby J.W.L.B. and the Class are without fault, and the injuries to Plaintiffs,

Baby J.W.L.B. and the Class would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

434. The aforementioned conduct of Defendants proximately caused damage to Plaintiffs, Baby J.W.L.B. and the Class.

COUNT III - CIVIL CONSPIRACY

435. Plaintiffs reassert the allegations in the foregoing paragraphs as if fully set out herein.

436. The Pharmaceutical Defendants continuously supplied prescription opioids to the Distributor Defendants despite having actual or constructive knowledge that said Distributors were habitually breaching their common law duties and violating the CSA. The Distributor Defendants continuously supplied prescription opioids to pharmacies despite having actual or constructive knowledge that said pharmacies were habitually breaching their common law duties and violating the CSA.

437. Without the Distributor Defendants' supply of prescription opioids, pharmacies would not be able to fill and dispense the increasing number of prescription opioids throughout Oklahoma.

438. No Defendant in this opioid network would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party, and none would have succeeded so significantly without engaging in the wrongful conduct as herein alleged.

439. The Pharmaceutical Defendants likewise benefitted from this distribution conspiracy in that the more pervasive opioid diversion became, the more the Pharmaceutical Defendants profited. Despite access to the same information in the hands of the Distributor Defendants, the Pharmaceutical Defendants ignored the warning signs of opioid diversion.

440. As a result of the concerted actions between and among the Defendants, the Plaintiff

and the class have suffered damages.

441. Plaintiffs, Baby J.W.L.B. and the Class demand judgment against each Defendant for compensatory damages.

COUNT IV - INJUNCTIVE AND EQUITABLE RELIEF OF MEDICAL MONITORING AND CONTINUING TREATMENT

442. Plaintiffs reassert the allegations in the foregoing paragraphs as if fully set out herein.

443. By definition, Baby J.W.L.B. and the Class were exposed to opioids, a known toxic substance, at a concentration higher than expected for the general population and suffer the physical injury of NAS.

444. Baby J.W.L.B. and the Class face a lifetime of latent, dread medical and emotional conditions proven to be linked to in utero exposure opioids including but not limited to: brain damage, muscular-skeletal developmental disorders, speech and language disorders, cognitive developmental disorders, psychiatric disorders, emotional development disorders, behavioral disorders and increased risk of addiction.

445. Plaintiff Baby J.W.L.B. and the Class will benefit from medical monitoring for the aforementioned medical and emotional conditions because testing and continued monitoring will bring to light the onset of these medical and emotional conditions so that treatment and intervention may begin at the earliest point possible.

446. Baby J.W.L.B. and the Class will benefit from a medical monitoring program featuring an epidemiological component that collects and analyzes medical monitoring results[5] so that other heretofore unrecognized latent, dread diseases that may be associated with in utero exposure may be identified so that treating professionals may better care for the Class Members and so that medical

[5] Such epidemiological data will be collected, maintained and analyzed in such a manner as to protect the identity of individual class members.

professionals engaged in the research and development of new treatment will have access to a broader universe of data.

447. Further, Baby J.W.L.B. and the Class will require on-going care for the aforementioned conditions which are known to result from in utero exposure to opioids including but not limited to medical care, psychiatric care, psychological care, physical therapy, cognitive therapy and speech therapy.

448. The harm visited upon Baby J.W.L.B. and the Class is irreparable.

449. Money damages will not suffice because it is impossible to predict with any certainty the costs of such monitoring and treatment for each individual class member nor is it possible to predict new treatment and intervention protocol that may be developed as data from medical monitoring of the Class is provided to the medical research community.

450. Further, money damages will not suffice because an award of money damages for future monitoring and treatment would not result in comprehensive programs whereby important information is shared among the medical community so that new treatments, protocols, intervention and test may be developed.

451. Plaintiffs, on behalf of all those similarly situated, seek a Court administered fund replenished from time-to-time by the Defendants to achieve such injunctive and equitable relief as necessary for the continuing benefit of the class.

452. Plaintiffs and the Class also seek injunctive relief, including enjoining the Defendants and all other persons acting in concert or participation with them from engaging in unfair or deceptive practices in violation of law as described herein, and by temporary, preliminary or permanent injunction force the Defendants and all other persons acting in concert or participation with them to abide by the Controlled Substances Act, provide the required control measures, and prevent unauthorized users from obtaining opioids.

453. Given the immense wealth of the Defendants, such injunctive and equitable relief presents no undue burden or irreparable damage to the Defendants.

COUNT V - PRODUCTS LIABILITY

454. Plaintiffs reassert the allegations in the foregoing paragraphs as if fully set out herein.

455. At all times material to this action, Defendants were engaged in the business of the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of opioid products.

456. At all times material to this action, Defendants' opioid products were expected to reach, and did reach, consumers in the State of Oklahoma and throughout the United States, including Plaintiffs herein, without substantial change in the condition in which they were sold.

457. Defendants knew that the damage causing characteristics of Defendants' product include its addictive properties on potential mothers and its in utero impacts on their future children.

458. Defendants knew that prolonged use of opioids leads to decreased effectiveness, requiring increases in doses to achieve the same level of pain relief, markedly increasing the risk of significant side effects and addiction. Defendants conducted studies documenting these risks, yet failed to publish the results or warn of the documented risks.

459. The risks of opioid addiction and the risk to children in utero are grave and Defendants had a duty to warn about these risks.

460. Providing such warnings would have been easily feasible, but would have interfered with Defendants' marketing efforts. Instead, Defendants' engaged in a multimillion dollar marketing and advertising effort promoting falsehoods and minimizing the risk of addiction and withdrawal from long term opioid use.

461. Defendants knew that opioids are too addictive and too debilitating for long-term use for chronic pain, barring exceptional circumstances. Defendants knew that the only safe uses for their

product were end of life care, short term pain relief after surgery, and pain relief related to cancer. Defendants failed to warn Oklahoma physicians, potential mothers and pregnant women of the dangers of using their product outside of these areas.

462. Defendants' products were unreasonably dangerous at the time they left the control of Defendants because of inadequate warning.

463. Because of Defendants' knowledge of the risks to mothers and their neonatal children, and their extensive efforts to obscure these risks, Defendants are liable for all resulting damages caused to Plaintiffs and the Class.

464. The opioid product manufactured and/or supplied by Defendants were defective in design in that an alternative design exists that would prevent addiction, NAS and severe and permanent injury to pregnant women and their unborn children.

465. A reasonably prudent manufacturer or seller would not have put Defendants' products on the market had it known of the products' dangerous condition and/or defective design.

466. Defendants designed their product in such a way that it could easily be abused by crushing of pills with the resulting powder ingested by inhalation or injection.

467. Defendants were aware that their products were being abused in this manner on a large scale, making this a reasonably anticipated use.

468. Despite this knowledge, Defendants only recently altered the design of their product to be "enteric," that is, changed it to a form that prevented such crushing and consumption. This change was only made after years of public and legal pressure.

469. Further, Defendants promoted their unreasonably dangerous design by actively undercutting the prescription of alternative nonsteroidal anti-inflammatory drugs, pushing the misinformation that such non-opioid drugs were not effective for the treatment of long term pain.

470. Therefore, Defendants are liable for the damages caused to the Plaintiffs and the Class

by their opioid products' unreasonably dangerous and defective design and inadequate warnings of their opioids' addictive properties.

COUNT VI - PUNITIVE DAMAGES

471. Plaintiffs reassert each and every allegation set forth in all preceding paragraphs as if fully restated herein.

472. The conduct of Defendants as set forth herein was malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiffs. Plaintiffs and the Class are thus entitled to recover punitive damages against Defendants.

473. Defendants were malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiffs, in their activities and in failing to warn Plaintiffs of dangers well known to Defendants, which acts exhibited a deliberate disregard for the rights and safety of Plaintiffs.

474. Defendants realized the imminence of danger to Plaintiffs and other members of the public, but continued with deliberate disregard and complete indifference and lack of concern for the probable consequences of their acts.

475. As a direct result of Defendants' deliberate disregard for the rights and safety of others, gross negligence, malicious, oppressive, willful, wanton, reckless, and/or criminal indifference to civil obligations affecting the rights of others, including Plaintiffs, Plaintiffs suffered the injuries and dangers stated above.

476. Defendants' acts as described herein exhibited deliberate disregard for the rights and safety of others and were malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiffs. An award of punitive and exemplary damages is therefore necessary to punish Defendants, and each of them, and to deter any

reoccurrence of this intolerable conduct. Consequently, Plaintiffs are entitled to an award of punitive damages.

477. The conduct of Defendants as set forth herein was malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiffs. Plaintiffs and the Class are thus entitled to recover punitive damages against Defendants in an amount sufficient to punish Defendants for their wrongful conduct and to deter Defendants and others from similar wrongful conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Putative Class Representative Samantha DeMaro, individually and on behalf of Baby J.W.L.B. and all those similarly situated requests that the Court grant the following relief:

a. Injunctive and Equitable Relief of Medical Monitoring and Continuing Treatment;

b. Injunctive Relief, including enjoining the Defendants and all other persons acting in concert or participation with them from engaging in unfair or deceptive practices in violation of law as described herein, and by temporary, preliminary or permanent injunction force the Defendants and all other persons acting in concert or participation with them to abide by the Controlled Substances Act, provide the required control measures, and prevent unauthorized users from obtaining opioids;

c. Compensatory damages;

d. Restitution;

e. Punitive damages;

f. Attorneys' fees and costs;

g. Pre and Post Judgment Interest;

h. All such other relief this Court deems just and fair; and

i. Plaintiff seeks a trial by jury for all counts so triable.

Respectfully submitted by:

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