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

DARREN AND ELENA FLANAGAN,
INDIVIDUALLY AND AS NEXT FRIEND
AND GUARDIAN OF BABY K.L.F.,

AND

SHARON A. WALKER AND DAVID S. WALKER,
INDIVIDUALLY AND AS NEXT FRIEND
AND GUARDIAN OF BABY C.W.,
ON BEHALF OF THEMSELVES
AND ALL OTHERS SIMILARLY SITUATED,

Plaintiffs,

MDL No. 2804
CASE NO. 1:18-op-45405-DAP
Judge Dan Aaron Polster

v.

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;
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,
DEPOMED, INC.;
MALLINCKRODT LLC;
MALLINCKRODT PLC;
SPECGX LLC;
PAR PHARMACEUTICAL, INC.;

CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED

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;
H.D. SMITH, LLC;
H.D. SMITH HOLDINGS, LLC;
H.D. SMITH HOLDING COMPANY; and
ANDA, INC.;

Defendants.

SECOND AMENDED CLASS ACTION COMPLAINT

NOW COME Plaintiffs and Putative Class Representatives Sharon and David Walker, as the next friend and guardian of Baby C.W., individually and on behalf of all others similarly situated, and Individual Plaintiffs Darren and Elena Flanagan, as the next friend and guardian of Baby K.L.M., and hereby file their Second Amended Complaint against Defendants for damages and equitable, statutory, and injunctive relief. In support thereof, Plaintiffs state as follows:

INTRODUCTION

1. Like thousands of children born every year, Baby K.L.M. and Baby C.W. ("**Baby Plaintiffs**") were born dependent on opioids. Prenatal exposure to opioids causes severe withdrawal symptoms and lasting developmental impacts. The first days of Baby Plaintiffs' lives were spent in excruciating pain as doctors weaned them from opioid addiction. Baby Plaintiffs will require years of treatment and counseling to deal with the effects of prenatal exposure. Baby Plaintiffs and their

mothers are victims of the opioid crisis that has ravaged Tennessee, causing immense suffering to those born addicted to opioids and great expense to those forced to deal with the aftermath.

2. At birth, Baby Plaintiffs were each diagnosed with Neonatal Abstinence Syndrome ("NAS"),[1] arising from their mother's dependence, oftentimes an addiction, upon opioids. Baby Plaintiffs were forced to endure a painful start to their lives: crying excessively, arching their backs, refusing to feed, and shaking uncontrollably. NAS is a clinical diagnosis and best described as "a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy."[2] Baby Plaintiffs spent their first days in a Neonatal Intensive Care Unit ("NICU") writhing in agony as they endured detoxification and withdrawals from powerful opioids. Baby Plaintiffs underwent Opioid Replacement Therapy to wean the newborn from its involuntary addiction. Such treatment, while medically necessary to save the child's life and lessen its suffering, prolong the negative health outcomes associated with their respective mother's ingestion of opioids..

3. Baby Plaintiffs' mothers were prescribed Defendants' opioids prior to their gestation, resulting in their mothers' opioid addictions and Baby Plaintiffs' opioid exposure during gestation.

4. Upon information and belief, Plaintiffs' mothers consumed opioids manufactured and distributed by one or more of the named defendants, including:

a. Cephalon's products Actiq and Fentora;

b. Janssen's product Duragesic;

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[1] The term "NAS" is defined to include additional, but medically-symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids from in utero exposure. Additional specifics on these readily identifiable and ascertainable terms will be provided in Plaintiffs' Motion for Class Certification.

[2] 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.

c. Endo's products Percodan, Percocset, Opana, Opana ER,[3] Oxycodone, Hydrocodone (Vicodin and Lortab), Oxymorphone, and Hydromorphone; and

d. Actaivis' product, Norco and Kadian.

5. Baby Plaintiffs' experiences are part of an opioid epidemic sweeping through the United States, including Tennessee, causing thousands of infants to experience great suffering and continuing developmental issues. This epidemic is the largest health care crisis in U.S. history.

6. 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.

7. Plaintiffs further seek the equitable relief of medical monitoring to provide this class of infants the monitoring of developmental issues that they each will inevitably confront as they grow older and, separately, injunctive relief aimed at reducing the chance of Baby Plaintiffs and those similarly situated becoming exposed to opioids in utero.

8. At all relevant times, Defendants manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to accurately represent the benefits and risks associated with the use of the prescription opioid drugs. The net result of this behavior was to flood the market with highly addictive, dangerous opioids, whether through the primary prescription market (including to females of child-bearing age) or the secondary market. At all times, Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious

[3] "ER" stands for Extended Release.

orders. But for the dereliction of this legal duty, the robust secondary market for opioids could not have existed.

PARTIES

A. Plaintiffs

9. Baby Plaintiffs are individuals who have suffered NAS as a result of exposure to opioids in utero. This drug exposure provides Baby Plaintiffs the right to sue, through their next friends and guardians, for equitable and injunctive relief under RICO, Tennessee's Drug Dealer Liability Act, public nuisance, and civil conspiracy. Plaintiffs assert individual, non-class damages under negligence and gross negligence.

10. Individual Plaintiffs Darren and Elena Flanagan are the adoptive parents of Baby K.L.F., who was born in Tennessee three years ago. Baby K.L.F. spent her first days in a NICU writhing in agony as she went through detoxification, going on to spend five weeks there while his withdrawal symptoms were treated by opioid replacement therapy. Upon information and belief, Baby K.L.F.'s mother was prescribed Defendants' opioids and her addiction began prior to Baby K.L.F.'s gestation. After becoming addicted to Defendants' prescription opioids, Baby K.L.F.'s mother illegally sold opioids on the street. Baby K.L.F.'s mother resided and purchased these opioids in Tennessee.

11. Plaintiffs and Class Representatives Sharon A. Walker and David S. Walker are the adoptive parents of Baby C.W., who was born on October 13, 2015 at Regional One Health in Memphis, Tennessee. Baby C.W. was exposed in utero due to his birth mother's consumption of opioids. Baby C.W.'s mother overdosed on opioids, twice, during the pregnancy. Baby C.W. was diagnosed with NAS and spent the next eight days crying inconsolably in the NICU where his

withdrawal symptoms were treated using a morphine drip to wean him off the opioids; i.e., the opioid replacement therapy. Baby C.W. suffers severe damages due to his in utero opioid exposure. For instance, he suffers an absent septum pellucidum, a form of congenital brain damage, in addition to severe, developmental delays and hearing loss.

12. Plaintiffs and Putative Class Members directly and foreseeably sustained all damages alleged herein. Categories of past and continuing sustained class-wide damages include equitable relief of medical monitoring and testing for latent dread diseases associated with NAS as well as injunctive relief aimed at protecting the Putative Class from irreparable harm.

13. Plaintiffs and 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

14. 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 Tennessee.

15. 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 Tennessee.

16. AmerisourceBergen Corporation ("**AmerisourceBergen**") 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 Tennessee.

17. 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 Tennessee, that sell prescription medicines, including opioids. At all times relevant to this Second Amended Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Tennessee.

18. 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**."

19. 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 Tennessee, that sell prescription medicines, including opioids. At all times relevant to this Second Amended 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 Tennessee.

20. 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**."

21. 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 Tennessee.

22. 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 Second Amended Complaint, Wal-Mart distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Tennessee.

23. 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 Tennessee.

24. 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 Tennessee and nationwide, prescription opioids including the Opioid Drugs at issue in this lawsuit.

25. 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 Second Amended Complaint, H. D. Smith distributed prescription opioids throughout the United States, including Tennessee.

26. 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 Tennessee. In October 2016, Defendant Teva Pharmaceuticals USA, Inc. acquired Anda for $500 million in cash. At all relevant times, Anda distributed prescription opioids throughout the United States, including in Tennessee.

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

Pharmaceutical Marketing and Manufacturing Defendants

28. 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 Tennessee. 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.

29. 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.

30. 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 Tennessee, 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 Tennessee, 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 Tennessee 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, Teva Ltd. would conduct those companies' business in Tennessee 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**.")

31. 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 Tennessee, including the opioid Duragesic, a fentanyl transdermal patch. 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.

32. 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. Until 2016, Noramco wholly owned Tasmanian Alkaloids, Inc., the largest opium poppy producer in the state of Tasmania, Australia. During Noramco's ownership of Tasmanian Alakloids, Noramco processed and imported Active Pharmaceutical Ingredients ("APIs") necessary for the production of opioid drugs

to the United States and sold these APIs to Janssen and various other domestic opioid manufacturers.

33. Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. ("EPI") is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. 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. 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 EHS and EPI. (EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates 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 Tennessee. 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 Tennessee, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

34. 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 Tennessee. 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 Tennessee. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

35. 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 Tennessee 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.

36. 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.

37. Defendant Indivior, Inc. ("**Indivior**") is a Delaware domestic corporation with its principal place of business in Richmond, Virginia. Indivior 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. Indivior, Inc. is a subsidiary of Indivior, PLC, based in the United Kingdom. Indivior, Inc. was formerly known as Reckitt Benckiser Pharmaceuticals, Inc. Indivior, Inc. has manufactured and/or labeled Buprenorphine shipped to Tennessee.

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

JURISDICTION AND VENUE

39. 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 Plaintiffs of this putative class action, citizens of the State of Tennessee, 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 as often as every 15 minutes.

40. This Court has personal jurisdiction over Defendants, each of which has committed torts, in part or in whole, within the State of Tennessee, as alleged herein. Moreover, Defendants have substantial contacts and business dealings directly within Tennessee by virtue of their distribution, dispensing, and sales of prescription opioids.

41. Plaintiffs reserve the right to move for transfer to the Western District of Tennessee at the conclusion of pretrial proceedings and assert that Tennessee law applies.

BACKGROUND FACTS

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

43. Opioids or opiates include any of various sedative narcotics containing opium or one or more of its natural or synthetic derivatives.

44. 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."

45. The Controlled Substances Act ("CSA") defines "opiate" or "opioid" as "any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining ability."

46. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the CSA. 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).

47. 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.

48. However, the past two decades have been characterized by increased abuse and diversion of prescription drugs, including opioid medications, in the United States.

A. The Opioid Epidemic

49. Prescription opioids have now become widespread. Opioids are the most-prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.

50. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.

51. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older – a total of 12 million people – reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health.

52. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention ("CDC") declared prescription painkiller overdoses at epidemic levels. Specifically, the CDC reported that the death toll from overdoses of prescription painkillers has more than tripled in the past decade and more than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

53. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.

54. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.

55. The President of the United States declared an opioid and heroin epidemic the same year.

56. The CDC released a report analyzing opioid-related hospital emergency department data between July 2016 and September 2017 and finding that nearly two thirds (66.4%) of drug overdose deaths in 2016 involved prescription opioids, illicit opioids, or both, an increase of 27.7% from 2015.

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

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

59. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare." The

economic burden of prescription opioid misuse alone is $78.5 billion a year, including costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.

60. The epidemic of prescription pain medicine and heroin deaths is devastating families and communities across the country. Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while billions of dollars of injury are caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

61. The prescription opioid manufacturers and distributors, including Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or contributing to the national, state, and local opioid epidemic.

B. Neonatal Abstinence Syndrome

62. Many of the victims of the opioid epidemic, and certainly some of the most harmed, are babies born with Neonatal Abstinence Syndrome. NAS babies experience DNA changes at the cellular level, particularly in the tissues of the brain and nervous system and suffer lifelong afflictions as a result of maternal use of prescription opioid medications during gestation. These patients require extensive care because NAS is associated with, for instance, permanent mental health problems and disorders, developmental impairment and cognitive deficits, and physical health limitations and deformities.

63. 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 healthcare for opioid exposed mothers and their babies is a major factor in the nation's rising unreimbursed healthcare costs.

64. 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 with NAS by 2012. Currently, the best estimates are that a child with NAS is born as frequently as every 15-25 minutes, depending upon the time period referenced.

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

66. In 2014, the number of babies born drug-dependent had increased by 500 percent since 2000, and the number of children being placed in foster care due in part to parental drug abuse is going up — now it is almost one third of all child removals.

67. 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.

68. 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. The opioid crisis caused by Defendants served to fuel an epidemic of heroin use.

69. All NAS-diagnosed children are at increased risk for neuropsychological disfunction and disorders (separate and apart from physical deformities and disorders). The challenges presented to them and their caregivers at birth can be summarized as: "Do they catch up, remain at a disadvantage, or proceed to function even more poorly than their peers over time?" Unfortunately,

research arising from 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.

70. 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, diminished 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.

71. Several factors 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. The transmission of opioids across the placenta increases as gestation increases, and synthetic opiates cross the placenta more easily than semisynthetic opiates. NAS is the end result of the sudden discontinuation of prolonged fetal exposure to opioids.

72. NAS babies' mothers either directly purchase and consume prescription opioids from one or more Defendants in the primary market, or indirectly (but foreseeably) obtain them from other sources in the diversionary or secondary market. Each minor child suffers, and faces an increased risk of lifelong mental illness, mental impairment, and loss of mental capacity. The minor child's entire health, use of 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 at risk of being compromised and permanently impaired.

73. Plaintiffs seek equitable relief in the form of medical monitoring, in order to provide this class of infants with monitoring of the developmental issues confronting them as they mature. The ongoing and robust medical monitoring and medical surveillance 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, come together to research the latent negative health impacts of NAS and the need for medical surveillance (and the release of all Defendants' health studies) becomes evident.

74. Neonatal exposure to opioids necessarily results in medical needs that exist throughout the entire period of the adolescent development of the Putative Class Members. These needs absolutely exist for any child who had to be 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 and weaned from opioids must have robust medical monitoring, medical surveillance, and medical referral 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, Plaintiffs and the Class seek, inter alia, injunctive relief.

75. In a study from Florida, the number of newborns who had NAS and were admitted to the NICU increased 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.[4]

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

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

78. 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.

79. 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

[4] 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.

opioid epidemic in Tennessee. This is characterized as "opioid diversion" and creates a secondary market. 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.

80. 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 Defendants in this action share responsibility for perpetuating the epidemic and the exponential increase in the number of infants afflicted with NAS.

81. Defendants have foreseeably caused damages to Plaintiffs and Putative Class Members, including the costs of neo-natal medical care, additional therapeutic services, prescription drug purchases, and other treatments for NAS afflicted newborns, and counseling, therapy, and rehabilitation services after birth and into the future. Plaintiffs bring this civil action seeking class-wide injunctive relief and any other relief allowed by law against Defendants that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably damaged, and continues to damage, Plaintiffs and the Class.

THE RISK OF SERIOUS LATENT DISEASE TO THOSE EXPOSED TO OPIOIDS IN UTERO

82. By definition the Putative Class Members have sustained an exposure to opioids greater than that expected by members of the general population. As part of the anticipated claims process, each Class Member will be required to show medical records evidencing exposure to opioids.

83. NAS is a generalized multi-system disorder that produces a constellation of symptoms in neonates. Neonatal Abstinence Syndrome results from abrupt discontinuation (or absence) of opioids consumed by the mother during pregnancy at the infant's birth.

84. All infants born to mothers with opioid-use disorders are at risk for diagnosis of NAS. and there are no well-defined strategies to prevent NAS from occurring in at-risk infants.

85. Opioids represent a single class of exposures because they all cause their effects at the same receptors—those that mediate the effects of endogenous opiates.

86. Opioids represent a single class of chemical substances because their molecular structures are very similar.

87. Opioids have typical pharmacological effects which are common to the group: effects on the brain, the nervous system, and the gastrointestinal system.

88. The opioid compounds all act at the same biological receptors and mimic natural peptides that have powerful and wide-ranging activity in living systems. Thus, they can be considered a class of chemical drugs both in terms of their pharmacological dosage activity relationships and also their overall chemical structure.

89. All opioids aproduce addiction and dependence and cause withdrawal symptoms on removal. Their activity as modulators of neurological signaling make them especially dangerous in adults due to rebound effects, but they are now known also to have significant effects on fetal development since they alter the cellular signaling environment.

90. The effect of all opioids is produced through a single, common pathway – the opioid receptor. The opioid receptor system is ancient and highly conserved; it has been present since

jawed vertebrates first appeared at least 450 million years ago. Differences between opioid products and potency may exist, but their mode of action via the opioid receptor system is identical.

91. Fetal development relies on the balanced control of cell proliferation and cell death through apoptosis (or "programmed cell death").

92. It has been demonstrated scientifically that exposure to opiates will increase the rate of apoptotic cell death in developing biological systems. This represents a common mode of action which leads to the large plethora of adverse conditions associated with fetal opioid exposure, including sub-optimal brain maturation, a form of functional teratogenesis associated with reduced cognitive function

93. Perturbed apoptosis is also a contributory factor in gross fetal malformations. These include mid-line fusion defects such as cleft palate, spina bifida, and gastroschesis postnatally.

94. Apoptosis is also essential for normal heart development. The heart develops from a single tube into a four-chamber heart through a series of complex 'foldings'. Such foldings are produced by cellular proliferation on one side of a tube, accompanied by apoptosis on the other side. The assymetric growth rates thus producing folding.

95. It is clear that the mechanism of altered apoptosis rates leads to malformations in humans.

96. The standard of care for treating NAS babies is to provide supportive measures, and pharmacotherapy is often initiated to treat NAS babies' inability to sleep, lack of weight gain, inadequate caloric intake, extreme irritability, seizures and hypertonicity. If a neonate is treated with an opioid, the drug withdrawal has to be gradually tapered (weaning) as the infant regains the capacity for self-regulation. This is known as Opioid Replacement Therapy.

97. Buprenorphine and methadone are the most commonly used agents for Opioid Replacement Therapy.

98. Upon information and belief, the agents used in Opioid Replacement Therapy are manufactured and distributed by Defendants, thereby creating a revenue stream not only from addicting adults who obtained opioids from the street or through a prescription, but also creating a revenue stream for Defendants by treating the babies born addicted to opioids.

99. Although a widely-accepted treatment, Opioid Replacement Therapy in neonates is associated with a plethora of negative health impacts, including but not limited to reduced brain and somatic growth, intractable nystagmus, altered visual evoked potentials, delayed encephalopathy, respiratory depression, bradycardia, hypotension, urinary retention, reduced gut motility, and emesis.

100. Specifically, buprenorphine, has been associated with extremely poor outcomes in children up to the age of 3 to whom the drug was prescribed including congenital heart disease, urinary collecting system defects, ophthalmic defects, and maxillofacial defects.

101. Major risks from prenatal opioid exposure include birth defects and physical disorders, altered brain development, and NAS. NAS can cause latent defects to the muscular-skeletal system, the digestive system, the cardio-vascular system, and the nervous system.

102. A National Birth Defect Prevention Study published in 2010 provides evidence that opioids behaved as predicted and caused major birth defects. The study looked at 17,449 cases and 6,701 controls. Statistically significant effects were found for associations between early pregnancy maternal opioid analgesic treatment and certain birth defects, notably heart defects, anencephaly, cleft palate, and spina bifida.

103. Long-term cognitive development is impaired in children born with NAS. Further, those children face a significantly increased risk of mental, speech/language, and emotional disorders.

104. Children born with NAS face increased risk of falling prey to the disease of opioid dependence and addiction.

105. These known risks create a need in the NAS population for medical monitoring.

106. While much is known about the risks of serious latent disease faced by children born with NAS who underwent Opioid Replacement Therapy, recent animal studies have revealed evidence of the following additional negative health outcomes:

a. increased incidence of neural tube defects

b. severe heart defects

c. spina bifida

d. impaired nerve mylenation

e. reduced regional brain volumes in the basal ganglia

107. The aforementioned risks of serious latent negative health impacts were published and widely-available but, inexplicably, neither disclosed nor even mentioned in the Pharmaceutical Defendants' marketing materials, package inserts, label warnings, unbranded research, captive advocacy group communications, FDA applications, FDA filings, or any other means of communication. This information was also available to the Distributor Defendants.

108. The Defendants purposely misrepresented that there were no teratogenic or mutagenic effects associated with the use of opioids to increase their profits.

109. The Defendants purposely misrepresented the potential of opioids to result in the negative health impacts described above.

OPIOID MARKETS

110. Defendants' pathway to maximizing profits were constrained only by the amount of medically necessary opioids that could be sold through controlled channels. The stark reality Defendants faced in terms of maximizing profits was that they could only sell so many prescription opioids to dying cancer patients. "The logic was simple: While the number of cancer patients was not likely to increase drastically from one year to the next, if a company could expand the indications for use of a particular drug, then it could boost sales exponentially without any real change in the country's health demography." And, without a new and robust primary market, there would be no supply for the secondary "spill-over" diversionary market that they intended.

1. Once exposed, users of the opioids could easily transition into the secondary market, which was necessarily supplied from the primary market, and which Defendants were legally charged with insuring there was no supply for. Soon, the demand from the secondary market was further driving prescriptions written for the primary market.

2. Thus began the Pharmaceutical Manufacturer and Marketing Defendants' quest to open a new primary market for opioid prescriptions: treatment of (a) chronic, (b) widespread pain (c) without dose limits. And, their "ace in the hole" was this: not only could they convince physicians to write prescriptions into this new market they could ensure, through the insidious mechanism of addiction, that patients like Tennessee women of child-bearing age would have to keep coming back for more. With the insidious power to create both unlimited supply AND unlimited demand for

these highly-addictive substances, the Pharmaceutical Defendants set out to create the new primary market. Each of the elements of the new primary market was selected to maximize sales and profits of the highly addictive drugs.

3. Pharmaceutical Defendants are the architects of the transition from a limited market pool of disease and injury (i.e., cancer, disorders requiring surgery, etc.) to widespread use to treat an ever-enlarging pool of common, non-life threatening, maladies and conditions, such as arthritis, back pain, and joint pain. Thus, the universe of targeted patient conditions could be vastly expanded by Pharmaceutical Defendants.

4. Next up was the Pharmaceutical Defendants' successful promotion of highly addictive opioids for chronic, i.e., long-term conditions; this step was critical to ensuring that the newly targeted patient conditions would not result in one-time sales.

5. Finally, to ensure even further sales growth and profits, the Pharmaceutical Defendants promoted the notion that there were no dose limits and, indeed, that patients who appeared to be addicted were actually patients who should be given even more and higher dosages for opioids.

6. In order to maximize profits, the Pharmaceutical Defendants collectively had to convince physicians to expand treatment of their patients to include chronic and "non-malignant", i.e., non-cancer, pain. And, the Pharmaceutical Defendants engaged in this activity despite the fact that the benefits of opioids are minimal in comparison to known risks, which are extreme even fatal.. Prospective, randomized, controlled trials lasting at least 4 weeks that evaluated the use of opioids for chronic non-cancer-related pain showed only a negligible to modest improvement in pain-relief and no consistent improvement in physical functioning. The maximal adverse risks, however, are a

witches' brew known to include a "high incidence of opioid abuse behaviors" and "addiction."

7. The market innovator that "inspired" all other Pharmaceutical Defendants to follow was Purdue,[5] the maker of OxyContin. And, it was not pharmacological innovation in which it led but marketing innovation.

> i. Arthur Sackler [the founder of Purdue, along with his two younger brothers Mortimer and Raymond] thriv[ed] … in the fledgling field of pharmaceutical advertising. It was here that he would leave his greatest mark. As a member of … a small New York-based advertising firm, Sackler expanded the possibilities of medical advertising by promoting products in medical journals and experimenting with televisions and radio marketing. Perhaps his greatest achievement, detailed in his biography in the Medical Advertising Hall of Fame, was finding enough different uses for Valium to turn it into the first drug to hit $100 million in revenue.
>
> ii. (…)
>
> iii. Sackler was also among the first medical advertisers to foster relationships with doctors in the hopes of earning extra points for his company's drugs, according to a 2011 expose in *Fortune*. Such backscratching in the hopes of reciprocity is now the model for the whole drug marketing industry.
>
> iv. Starting in 1996, Purdue Pharma expanded its sales department to coincide with the debut of its new drug.… Purdue increased its number of sales representatives from 318 in 1996 to 371 in 2000. By 2001, when OxyContin was hitting its stride, these sales reps received annual bonuses averaging over $70,000, with some bonuses nearing a quarter of a million dollars. In that year, Purdue Pharma spent $200 million marketing its golden goose.

[5] Bankruptcy protection has been sought by former Defendants to this action Purdue Pharma, L.P., Purdue Pharma, Inc., and The Purdue Frederick Company. While Plaintiffs are pursuing creditor relief in that proceeding against those parties, a discussion of the Purdue entities is helpful to understanding both the concert of action and unified scheme waged by the entire industry, especially given that Purdue was a "leader" and "early adopter" of so many nefarious activities that were replicated by Defendants.

Other persons/entities related to unnamed co-conspirator Purdue include 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 Pharmaceuticals Inc., Trust for the Benefit of Members of the Raymond Sackler Family, and The P.F. Laboratories, Inc.

v. Boots on the ground was not the only stratagem employed by Purdue to increase sales for OxyContin. Long before the rise of big data, Purdue was compiling profiles of doctors and their prescribing habits into databases.

vi. (…)

vii. Between physician databases, incentive-happy sales reps, and an aggressive blitz package of promotional ephmerea, Purdue's multifaceted marketing campaign pushed OxyContin out of the niche offices of oncologists and pain specialists and into the primary care bazaar, where prescriptions for the drug could be handed out to millions upon millions of Americans. The most scathing irony is that what allowed OxyContin to reach so many households and communities was the claim that it wasn't dangerous.[6]

8. Concurrent with the innovative marketing techniques of Purdue, were the efforts of the entire industry to secure a highly potent and stable supply of the active pharmaceutical ingredient (API) in opioids. Upon information and belief, Janssen actively conspired with other pharmaceutical manufacturer and distributor defendants to significantly increase the supply of powerful opioid drugs in the market, thereby exacerbating the opioid epidemic. *See* Findings of Fact No. 6 through 15, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816. In a quest to dominate the growing opioid market, J&J grew poppies in Tasmania, Australia, and imported and sold APIs derived from these poppies necessary for the manufacture of opioid drugs to other manufacturer defendants. *See* Findings of Fact No.9 through 11, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816

9. The Pharmaceutical and Distributor Defendants had an absolute and non-delegable duty to ensure that a supply of controlled substances for a secondary market did not exist. To be clear, the diversion and misuse of controlled substances is a known high-risk factor with significant

[6] Mike Mariani, "How the American Opiate Epidemic Was Started by One Pharmaceutical Company," *Pacific Standard*, March 4, 2015.

negative consequences for families, communities, and even entire states. When a manufacturer or distributor who wants to deal in controlled substances registers with the DEA, they must take on a duty to prevent the known negative health effects of their addictive products.

10. In the case of prescription opiates, not only did Defendants wholly fail in that duty, but they intentionally endeavored to flood the primary market with such an excess of drugs that they either knew, or consciously and willfully disregarded the fact, that this would result in misuse and diversion into a secondary market.

11. Flooding an entire country with this many highly addictive opiates did not occur by accident. Instead, it occurred as the result of a highly coordinated, expensive, misleading, illegal, and callous manipulation of both the sales and distribution schemes for controlled substances within the United States.

PHARMACEUTICAL DEFENDANTS' WRONGFUL CONDUCT

12. As Senator McCaskill aptly recognized:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.

13. To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and fraudulent marketing and 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 deceptive, false, and unfair. They were not supported by, and in fact contrary to, the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence.

14. The Pharmaceutical Defendants spread their false, deceptive, and unfair statements by marketing their branded opioids directly to doctors and patients in Tennessee. In fact, they specifically targeted susceptible prescribers and vulnerable patient populations, including those in Tennessee. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false, reckless, and/or negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of Tennessee.

15. The Pharmaceutical Defendants' direct and branded advertisements falsely 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. While Endo agreed in 2015-16 to stop these particularly misleading representations in New York, they continued to disseminate them in Tennessee.

16. 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.

17. 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.

18. 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 gave the false impression that they were providing unbiased and medically accurate presentations when they were, 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.

19. 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.

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

21. The Pharmaceutical Defendants negligently marketed opioids in Tennessee through unbranded advertising that promoted opioid use generally yet was silent as to any 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.

22. 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.

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

24. 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.

25. The Pharmaceutical Defendants also 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 Foundation ("APF"), American Academy of Pain ("AAP"), American Pain Society ("APS"), American Geriatrics Society ("AGS"), Federation of State Medical Boards

("FSMB"), U.S. Pain Foundation ("USPF"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

26. Patient advocacy organizations and professional societies like these play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.

27. The Pharmaceutical Defendants collaborated, through the aforementioned organizations and groups, to spread false, reckless, and/or negligent messages about the risks and benefits of long-term opioid therapy. The relationships between the Pharmaceutical Defendants and these groups is further described below:

28. APF was the most prominent member of the seemingly independent groups the Pharmaceutical Defendants used and was funded almost exclusively by the Pharmaceutical Defendants, receiving more than $10 million in funding from the Pharmaceutical Defendants between 2007 and the close of its business in May 2012. APF had multiple contacts and personal relationships with the Pharmaceutical Defendants through its many publishing and educational programs, funded and supported by the Pharmaceutical Defendants. On information and belief, between 2009 and 2010, APF received more than eighty percent of its operating budget from pharmaceutical industry sources. By 2011, upon information and belief, APF was entirely dependent on incoming grants from Defendants Cephalon, Endo, and others.

29. On information and belief, APF was often called upon to provide "patient representatives" for the Pharmaceutical Defendants' promotional activities, including for Janssen's

"Let's Talk Pain." APF functioned largely as an advocate for the interests of the Pharmaceutical Defendants, not patients.

30. APF is also credited with creating the the Pain Care Forum ("PCF") in 2004. On information and belief, former APF President Will Rowe described the PCF as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

31. Upon information and belief, representatives of the Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

32. In December 2011, a ProPublica investigation found that in 2010, nearly 90% of APF's funding came from the drug and medical device community, including Pharmaceutical Defendants. More specifically, APF received approximately $2.3 million from industry sources out of total income of $2.85 million in 2009. Its budget for 2010 projected receipt of approximately $2.9 million from drug companies, out of total income of approximately $3.5 million. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

33. The American Academy of Pain Medicine ("AAPM") was another group that had systematic ties and personal relationships with the Pharmaceutical Defendants. AAPM's corporate council includes Depomed, Teva and other pharmaceutical companies. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations

council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM described the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allowed drug company executives and marketing staff to meet with AAPM executive committee members in small settings. The Pharmaceutical Defendants were all members of the council and presented deceptive programs to doctors who attended this annual event.

34. The Pharmaceutical Defendants internally viewed AAPM as "industry friendly," with Defendants' advisors and speakers among its active members. The Pharmaceutical Defendants attended AAPM conferences, funded its CMEs and satellite symposia, and distributed its publications. AAPM conferences heavily emphasized sessions on opioids.

35. Upon information and belief, representatives of the Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities and publications for AAPM to pursue. AAPM then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

36. APS was another group with systematic connections and interpersonal relationships with the Pharmaceutical Defendants. APS was one of the groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of "extensive ties between companies that manufacture and market opioids and non-profit organizations" that "helped created a body of dubious information favoring opioids."

37. Upon information and belief, representatives of the Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities and publications for APS to pursue. APS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

38. FSMB was another group with systematic connections and interpersonal relationships with the Pharmaceutical Defendants. A June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed substantial payments from the Pharmaceutical Defendants beginning in 1997 and continuing through 2012. Not surprisingly, the FSMB was another one of the groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of "extensive ties between companies that manufacture and market opioids and non-profit organizations" that "helped created a body of dubious information favoring opioids."

39. USPF was another group with systematic connections and interpersonal relationships with the Pharmaceutical Defendants. USPF was one of the largest recipients of contributions from the Pharmaceutical Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone. USPF was also critical to Defendants' lobbying efforts to reduce the limits on over-prescription. USPF advertised its ties to the Pharmaceutical Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, McNeil (i.e., Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members. Industry groups like AAPM, APS, and PhRMA are also members of varying levels in USPF.

40. AGS was another group with systematic connections and interpersonal relationships with Defendants. AGS was a large recipient of contributions from the Pharmaceutical Defendants, including Endo and Janssen. AGS contracted with the Pharmaceutical Defendants to disseminate

guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons) and 2009 (Pharmacological Management of Persistent Pain in Older Persons). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009. AGS internal discussions in August 2009 reveal that it did not want to receive upfront funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

41. Upon information and belief, representatives of the Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

42. The U.S. Senate found that the Pharmaceutical Defendants made nearly $9 million worth of contributions to various patient advocacy organizations and professional societies such as those described herein.

43. The Defendants also had systematic links to and personal relationships with each other through their participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities, including but not limited to, PCF and the Healthcare Distribution Alliance ("HDA").

44. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF, including the

Pharmaceutical Defendants, quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

45. PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.

46. Not surprisingly, each of the Pharmaceutical Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.

47. In 2012, membership and participating organizations in the PCF included the HDA (of which all the Pharmaceutical Defendants are members), Endo, J&J, and Teva.

48. AAPM, APF, and APS were also members of PCF.

49. The HDA is an industry trade assocation for wholesalers and distributors.

50. The benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."

51. The HDA also offered multiple conferences, including annual business and leadership conferences through which the Pharmaceutical Defendants had an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."

52. The Defendants met regularly through the PCF and HDA.

53. To convince doctors and patients in Tennessee 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 misrepresenting the risks and benefits of

long-term opioid use to those doctors and patients, these Defendants, themselves and through the above third-party organizations, made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

54. 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, but they continue to make them today.

55. The Pharmaceutical Defendants falsely 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 misrepresentations by opioid manufacturers are:

a. Actavis employed a patient education brochure that claimed opioid addiction is "less likely if you have never had an addiction problem";

b. Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain, claiming that addiction is rare and limited to extreme cases of unauthorized doses;

c. Endo sponsored a website, Painknowledge.com, which 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 claimed that concerns about opioid addiction are "overestimated";

g. Mallinckrodt's C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance promoted a book entitled Defeat Chronic Pain Now! which claimed that "[w]hen chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving" and "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance"; Janssen's website for Duragesic stated, "Addiction is relatively rare when patients take opioids appropriately," in response to a hypothetical patient's concern that he would "become a drug addict";

h. Depomed's Senior Vice President and Chief Financial Officer, August Moretti, told investors that "[a]lthough not in the label, there's a very low abuse profile and side effect rate" for Nucynta;

i. another Endo website, PainAction.com, stated that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them"; and

j. Janssen's unbranded website "Prescribe Responsibly" stated that concerns about addiction were "overestimated" and that "true addiction occurs only in a small percentage of patients."

56. 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."

57. 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]."

58. 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, and Dr. Russell Portenoy, KOLs for Cephalon, Endo, and Janssen. Defendants negligently claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these negligent claims are: (a) Cephalon 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;" and (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.

59. 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."

60. The Pharmaceutical Defendants recklessly and/or 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 the Pharmaceutical Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Pharmaceutical Defendants' misrepresentations were intended to make doctors more comfortable in prescribing opioids. Some examples of these claims are: (a) an Endo supplement in the Journal of Family Practice emphasized the effectiveness of screening tools to avoid addictions; (b) Cephalon sponsored a continuing medical education ("CME") resentation offered by Medscape in 2003 entitled Pharmacologic Management of Breakthrough or Incident Pain that taught that "[c]linicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse" and "[t]he concern about patients with chronic pain becoming addicted

to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse"; and (c) Mallinckrodt's C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance promoted a book entitled Defeat Chronic Pain Now! which asserted as "[t]he bottom line" that "[o]nly rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction" and as "fact[]" that "[i]t is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

61. 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."

62. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Pharmaceutical Defendants falsely 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.

63. The 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."

64. 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 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;" and (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.

65. These and other representations were not true, as now 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.

66. 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."

67. The 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.

68. The 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. Mallinckrodt advertised that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving" and "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive deterrent ingredients.

69. 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."

70. 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 misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false claims, they continue to make them today.

71. For example, the Pharmaceutical Defendants falsely and recklessly, and/or 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 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, recreating, having sex, walking, and climbing stairs; (d) Responsible Opioid Prescribing, by Cephalon and Endo, taught that relief of pain by opioids, by

itself, improved patients' function; (e) Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain, which counseled patients that opioids "give [pain patients] a quality of life we deserve"; (f) 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"; (g) 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"; and (h) 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."

72. 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." 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."

73. 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.

74. 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 one opioid manufacturer that it was "not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug 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 another 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."

75. 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. For example, APF's A Policymaker's Guide to Understanding Pain & Its Management, sponsored by Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months" and (falsely) attributed 10,000 to 20,000 deaths annually to NSAID overdose, with no corresponding warning for opioids.

76. 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.

77. Each Pharmaceutical Defendant has fraudulently, recklessly, and negligently marketed its opioids on numerous occasions. In addition to the specific representations and misconduct outlined above, Plaintiffs state the following:

Cephalon

78. In Tennessee and nationwide, Cephalon engaged in the manufacture, promotion, distribution, and sale its opioids Actiq and Fentora.

79. Cephalon negligently marketed 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.

80. 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, instructing 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 – that openly promotes Fentora for "multiple causes of pain" and not just cancer pain.

81. Cephalon's 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.

82. In summary, Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

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

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

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

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

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

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

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

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

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

Actavis

83. In Tennessee and nationwide, Actavis is engaged in the manufacture, promotion, distribution, and sale of opioids such as the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana.

84. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

85. Actavis negligently promoted Kadian through 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."

86. 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."

87. In summary, Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

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

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

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

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

Depomed

88. Depomed manufactured, promoted, distributed, and sold opioids throughout the United States, including in Tennessee.

89. 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.

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

91. 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.

92. When it launched Lazanda in 2011, Depomed'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 Lazanda-like drugs.

93. 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.

94. 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.

95. 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 writers. Depomed 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.

96. 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.

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

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

99. 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.

100. 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.

101. 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.

102. 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.

103. 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.

104. 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.

105. 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.

106. 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.

107. 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.

108. 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."

109. 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."

110. Depomed represented that Nucynta was uniquely positioned to combat the negative public sentiment against opioids. 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."

111. Depomed knew that it could not promote Nucynta as a safer, less addictive, less abusive opioid that did not have the same euphoric effect 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.

112. 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.

Endo

113. Endo develops, markets, and sells prescription drugs, including the branded opioids Opana/Opana ER, Percodan, Percocet, and Zydone and generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Tennessee.

114. Endo misrepresented the benefits of opioids for chronic pain. In addition to the numerous examples of such misrepresentations outlined above, 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.

115. A CME sponsored by Endo, entitled Persistent Pain in the Older Adult, also claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days.

116. 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 Tennessee.

117. In summary, Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

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

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

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

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

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

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

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

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

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

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

k. Directly distributing and assisting in the dissemination of literature that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain, including the concept of pseudo-addiction;

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

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

Mallinckrodt

118. In Tennessee 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.

119. 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.

120. 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.

121. 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."

122. 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.

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

124. 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.

125. Mallinckrodt, plc, Mallinckrodt, LLC and SpecGx, LLC and their subsidiaries are Pharmaceutical Defendants, and all allegations against the Pharmaceutical Defendants herein apply equally to Mallinkcrodt.

Johnson & Johnson Defendants

126. Since at least the mid-1990s, J&J, Janssen, and Normaco, have developed, produced, marketed, promoted, and sold opioid drugs and the ingredients for opioid drugs across the nation, including in Tennessee. Although changes in corporate structure and ownership evolved during the opioid crisis, the Johnson & Johnson Defendants independently and in concert contributed to the public nuisance created by their tortious acts.

127. Noramco 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 J&J also apply to Noramco. Moreover, Noramco is a Pharmaceutical Defendant, and all allegations against the Pharmaceutical Defendants herein apply equally to Noramco.

128. Janssen is a wholly owned subsidiary of J&J and its manufacturer of opioid drugs. All allegations pertaining to J&J also apply to Janssen. Moreover, Jansen is a Pharmaceutical Defendant, and all allegations against the Pharmaceutical Defendants herein apply equally to Janssen.

129. In addition to the numerous specific allegations outlined above, Janssen disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

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

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

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

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

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

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

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

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

i. Directly distributing and assisting in the dissemination of literature written that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain, including the concept of pseudo-addiction;

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

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

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

130. Moreover, as part of its marketing, promotion, and sale of opioid drugs, J&J specifically manufactured and sold opioid drugs through Janssen as part of its pain franchise, including (i) Duragesic transdermal patch made out of the active pharmaceutical ingredient ("API") fentanyl; (ii) Ultram and Ultram ER tablets made out of the APIs tramadol and acetaminophen; (iii)Ultracet – tablets made out of the APIs, tramadol and acetaminophen; (iv) Nucynta and Nucynta ER – tablets made out of the API, tapentadol; (v) Tylenol with Codeine-tablets made out of the APIs, acetaminophen and codeine; (vi) Tylox capsules made out of the APIs acetaminophen and oxycodone. *See* Finding of Fact No.4, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

131. This Court has found that sufficient evidence has been presented in this case to support a finding that Jansen engaged in misleading marketing activities that resulted in a substantial increase in the supply of prescription opioids and proximately caused harm to Plaintiffs. Additionally, this court has found that the record presented so far in this case could allow a jury to reasonably conclude that Janssen's unbranded marketing efforts were a substantial factor in producing the harm alleged by Plaintiffs. Further, this court has found that evidence has been produced upon which a jury could reasonably conclude that Janssen failed to maintain effective controls against diversion, and that these failures were a substantial factor in producing the harm suffered by plaintiffs. *See* Opinion and Order Denying Janssen's Motion for Summary Judgment, Case 1:17-md-02804-DAP, Doc #2567, filed 09/09/2019.

132. Dr. Paul Janssen, the founder of Janssen Pharmaceutica, now a subsidiary of J&J, originally invented fentanyl in the 1950s. Fentanyl, an extremely powerful opioid, is a major factor in the opioid crisis, related to rising numbers of overdose deaths as well as the increasing prevalence of NAS. *See* Finding of Fact No. 5, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

133. Janssen's opioid marketing, in its multitude of forms, was false, deceptive, and misleading. These marketing activities targeted both the public at large as well as physicians and the medical community directly. *See* Finding of Fact No. 44, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

134. Additionally, misinformation from Janssen's direct marketing to doctors influenced the medical community's prescribing practices and perception of the dangers of opioids, and encouraged doctors to liberally and aggressively write a higher number of opioid prescriptions. The rapid increase in the prescribing and sale of opioid drugs is directly and causally linked to negative consequences of the opioid epidemic, including addiction and overdose deaths as well as rising rates of NAS and children entering the child welfare system. *See* Findings of Fact No. 53 and 55, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

135. Upon information and belief, Janssen actively conspired with other Defendants to significantly increase the supply of powerful opioid drugs in the market, thereby exacerbating the opioid epidemic. *See* Findings of Fact No. 6 through 15, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

136. In a quest to dominate the growing opioid market, J&J grew poppies in Tasmania, Australia and imported and sold APIs derived from these poppies necessary for the manufacture of

opioid drugs to other manufacturer defendants. *See* Findings of Fact No.9 through 11, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

137. Beginning in 1990 and continuing until at least 2016, J&J wholly owned two subsidiaries, Noramco and Tasmanian Alkaloids Limited ("Tasmanian Alkaloids"), which supplied opioid manufacturers with the raw ingredients necessary to meet the growing demand for powerful opioid drugs as the opioid epidemic increased in severity. *See* Findings of Fact No. 11, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

138. As the opioid crisis worsened, Tasmanian Alkaloids engaged in the cultivation, breeding, and processing of opium poppy plants into compounds necessary for the production of opioid APIs in Tasmania. These raw ingredients were then imported to the United States by Noramco. *See* Findings of Fact No. 9 through 11, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

139. Noramco processed the raw ingredients into opioid APIs and sold them to opioid manufacturers. *See* Findings of Fact No. 12, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

140. Upon information and belief, J&J's activities in the production of raw opioid APIs included the development of the Norman Poppy, a strain of the plant containing high levels of the compound *Thebaine*, which is a critical ingredient for the production of oxycodone, oxymorphone, nalbuphine, naloxone, naltrexone, and buprenorphine. *See* Finding of Fact No. 14, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816

141. Upon information and belief, the high-Thebaine Norman Poppy was patented by Tasmanian Alkaloids in 1994 and "was a transformational technology that enabled the growth of

oxycodone." *See* Finding of Fact No. 11, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

142. Upon information and belief, Noramco sold opioid APIs to various other opioid manufacturers, including Teva and "all seven of the top US generic companies" through "long-term agreements." *See* Finding of Fact No. 14, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816

143. Upon information and belief, by 2016, when J&J transferred Noramco and Tasmanian Alkaloids to a private investment firm, Noramco was one of the nation's top suppliers of opioid APIs. In a 2015 presentation to potential buyers of the company, Noramco was described to potential buyers as the "#1 supplier of Narcotic APIs in the United States, the world's largest market." The same presentation lists Net Trade Sales for several of Noramco's APIs, including $94 million in Oxycodone and $52 million in hydrocodone in 2014 alone.

144. Upon information and belief, J&J's supplying of raw opioid ingredients enabled manufacturer defendants to meet the growing demand for powerful and dangerous opioid drugs formed in the wake of the pharmaceutical industry's misleading mass marketing of opioid drugs to the medical community and directly to the public. By enabling the large-scale manufacture of these drugs, J&J conspired to create an opioid epidemic, addicting millions of Americans to opioid drugs and significantly increasing instances of NAS in the U.S.

Indivior

145. Indivior 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.

Indivior has manufactured and/or labeled Buprenorphine shipped to Tennessee. Indivior is a Pharmaceutical Defendant, and all allegations against the Pharmaceutical Defendants herein apply equally to Indivior.

146. As demonstrated by the allegations above, 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.

147. The Pharmaceutical Defendants' fraudulent, reckless, and negligent marketing scheme caused and continues to cause doctors in Tennessee to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent 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.

148. The Pharmaceutical Defendants' fraudulent, reckless, and 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.

149. The escalating number of opioid prescriptions written by doctors who were deceived by the Pharmaceutical Defendants' marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Tennessee. 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."

150. 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."

151. 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.

152. The Pharmaceutical Defendants also failed to prevent diversion of the drugs they manufactured, and to monitor, report, and prevent suspicious orders of prescription opioids in accordance with federal law.

153. 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.

154. The DEA also targeted Mallinckrodt in 2011 about its failure to report suspicious orders of pills, as many as 500 million of which ended up in Florida between 2008 and 2012. Federal prosecutors summarized the case by saying that everyone at Mallinckrodt knew what was going on but did not think they had a duty to report it.

155. In the press release accompanying the settlement, the Department of Justice stated that Mallinckrodt did not meet its obligations to detect and notify the DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. The DOJ went on to state that these suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone, that Mallinckrodt's actions and omissions

formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street, and that manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands.The Department of Justice imposed fines against Mallinckrodt for $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.

156. Moreover, at all times relevant to this Second Amended 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 professional societies 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.

157. 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 Janssen, ran similar websites that masked their own direct role.

158. 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.

159. Thus, the Pharmaceutical Defendants successfully concealed from the medical community and patients 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.

160. This Court has found that Plaintiffs have presented sufficient evidence to support a finding that each Pharmaceutical Defendant engaged in misleading marketing activities that resulted in a substantial increase in the supply of prescription opioids and proximately caused harm to Plaintiffs. This Court has also found that Plaintiffs in this case have produced evidence upon which a jury could reasonably conclude that each Pharmaceutical Defendant failed to maintain effective controls against diversion, and that these failures were a substantial factor in producing the harm suffered by Plaintiffs. *See* Opinion and Order denying Janssen's Motion for Summary Judgment, Case 1:17-md-02804-DAP, Doc #2567, filed 09/04/2019. *See also* Opinion and Order Regarding Defendants' Summary Judgment Motions on Causation, Case 1:17-md-02804-DAP, Doc #2578, Filed 09/09/2019.

DISTRIBUTOR DEFENDANTS' WRONGFUL CONDUCT

161. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies. The

distributors then supply opioids to pharmacies, doctors, and other healthcare providers, who then dispense the drugs to patients.

162. The Pharmaceutical 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.

163. 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.

164. 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.

165. 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.

166. Every year, thousands of people in Tennessee misuse and abuse opioid pain relievers that can lead to addiction, NAS, overdose and death.

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

168. 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 a 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.

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

170. 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.

171. In addition to having common law duties, the Distributor Defendants are governed by the statutory requirements of the 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.

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

173. 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.

174. 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.

175. 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. 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.

176. 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.

177. 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.

178. 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.

179. 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 §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR § 1301.71.

180. 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 Tennessee law, as alleged herein.

181. 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.

182. 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 discussion. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management

Association ("HDMA") (now the HDA). 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.

183. On September 27, 2006 and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors, including the Distributor Defendants, 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.

184. 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.

185. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants, including the Distributor Defendants, 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.

186. The HDMA, the Distributor Defendants' own industry group, 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.

187. 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."

188. 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.

189. 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).

190. 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."

191. H.D. Smith has stated publicly that it "operates with stringent protection for our nation's healthcare supply chain. The company works with its upstream manufacturing and downstream pharmacy partners to guard the integrity of the supply chain, and to improve patient outcomes."

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

193. 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.

194. 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 CSA, as specifically outlined below.

195. Relying on 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.

196. Although distributors, including some Distributor Defendants, 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.

197. 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.

198. The Distributor Defendants have supplied massive quantities of prescription opioids in Tennessee 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.

199. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to flow into Tennessee 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).

200. 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 Tennessee; 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.

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

202. 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 Tennessee, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

203. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the consumer market of Tennessee with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

204. 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.

205. 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.

206. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed to patients and citizens of Tennessee 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.

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

208. The Distributor Defendants 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.

209. Having knowledge and/or notice of the damages that their conduct had caused to Plaintiffs and the Class, the Distributor Defendants failed to take other steps to help curb the damages already incurred by Plaintiffs. The Distributor Defendants 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; (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.

210. The Distributor Defendants could have and should have implemented these measures at any point in the last 15 years.

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

212. The failure to take action was negligent and did result in significant damages to Plaintiffs and the Class.

213. The Distributor Defendants made substantial profits over the years based on the diversion of opioids affecting Tennessee. 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.

214. 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.

215. Each Distributor Defendant has distributed excessive amounts of prescription opioids. In addition to the misconduct outlined above, Plaintiffs state the following:

Cardinal, McKesson, and AmerisourceBergen

216. Cardinal, McKesson, and AmerisourceBergen are licensed wholesale drug distributors who conduct business throughout the United States, including in Tennessee.

217. Cardinal, McKesson, and AmerisourceBergen together account for 85-90% of all revenues from drug distribution in the United States – an estimated $378.4 billion in 2015.

218. 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 CSA. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

219. 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.

220. 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."

221. In their capacity as wholesale distributors, Cardinal, McKesson, and AmerisourceBergen are Distributor Defendants, and all allegations against the Distributor Defendants herein apply equally to them.

CVS

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

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

224. 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.

225. 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.

226. 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.

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

228. 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.

229. 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.

230. 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.

231. 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.

232. 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.

233. 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."

234. 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.

235. 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.

236. 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.

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

238. 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.

239. In their capacity as wholesale distributors, CVS and its subsidiaries are Distributor Defendants, and all allegations against the Distributor Defendants herein apply equally to CVS.

Rite Aid

240. 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 Tennessee, that sell prescription medicines, including opioids.

241. At all times relevant to this Second Amended 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 Tennessee.

242. 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.

243. 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.

244. 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).

245. In their capacity as wholesale distributors, Rite Aid and its subsidiaries are Distributor Defendants, and all allegations against the Distributor Defendants herein apply equally to Rite Aid.

Walgreens

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

247. 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 year 2017.

248. 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.

249. 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.

250. 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. 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.

251. 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.

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

253. 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.

254. 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.

255. In their capacity as wholesale distributors, Walgreens and its subsidiaries are Distributor Defendants, and all allegations against the Distributor Defendants herein apply equally to Walgreens.

Wal-Mart

256. Wal-mart, through its various DEA registered affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Second Amended Complaint, Wal-Mart distributed prescription opioids throughout the United States, including in Tennessee.

257. In its capacity as a wholesale distributor, Wal-mart is a Distributor Defendant, and all allegations against the Distributor Defendants herein apply equally to Wal-mart.

Miami-Luken

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

259. 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.

260. 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.

261. 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.

262. In its capacity as a wholesale distributor, Miami-Luken is a Distributor Defendant, and all allegations against the Distributor Defendants herein apply equally to Miami-Luken.

Costco

263. Costco operates pharmacies throughout the United States, including in Tennessee.

264. 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.

265. 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…."

266. In 2017, Costco Wholesale was fined $11.75 million as a result of a multijurisdictional investigation by the DOJ relating to CSA violations.

267. 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.

268. In its capacity as a wholesale distributor, Costco is a Distributor Defendant, and all allegations against the Distributor Defendants herein apply equally to Costco.

H.D. Smith

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

270. H.D. Smith has also routinely been found to have violated its duties to report suspicious orders and halt suspicious shipments of prescription opioids.

271. Data provided to the U.S. House of Representatives Committee on Energy and Commerce showed that, between 2007 and 2008, H.D. Smith provided two pharmacies in Williamson, West Virginia, a town with a population of 3,191, a combined total of nearly 5 million hydrocodone and oxycodone pills, an amount sufficient to provide approximately 1,565 hydrocodone and oxycodone pills to every man, woman, and child in Williamson.

272. 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. Press accounts further indicate that H.D. Smith did not submit any suspicious order reports to the state of West Virginia for at least a decade. Upon information and belief, H. D. Smith engaged in similar wrongful activities in Tennessee.

273. In its capacity as a wholesale distributor, H.D. Smith is a Distributor Defendant, and all allegations against the Distributor Defendants herein apply equally to H.D. Smith.

Anda

274. 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, Teva

Pharmaceuticals USA, Inc. acquired Anda for $500 million in cash. At all times relevant to this Second Amended Complaint, Anda distributed prescription opioids throughout the United States, including in Tennessee.

275. In its capacity as a wholesale distributor, Anda is a Distributor Defendant, and all allegations against the Distributor Defendants herein apply equally to Anda.

DISCOVERY RULE AND TOLLING

276. 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. 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.

277. Discovering the nature and extent of 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

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

Children who are Tennessee residents, born after March 21, 2000, who were medically diagnosed as being exposed in utero to opioids, who were pharmacologically weaned from opioids and whose birth mother received a

prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant and/or unnamed, co-conspirator affiliated with Purdue Pharma.[7]

Strictly in the alternative, and only if the Court finds that additional refinement of the class definition is necessary, Plaintiffs propose the following additional subclass definitions:[8]

a. Tennessee residents born after March 21, 2000, who were medically diagnosed as being exposed in utero to opioids, who were pharmacologically weaned from opioids and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Cephalon Defendants";[9]

b. Tennessee residents born after March 21, 2000, who were medically diagnosed as being exposed in utero to opioids, who were pharmacologically weaned from opioids and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Endo Defendants;"[10]

c. Tennessee residents born after March 21, 2000, who were medically diagnosed as being exposed in utero to opioids, who were pharmacologically weaned from opioids and

[7] Unnamed, co-conspirators affiliated with Purdue include Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, 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 Pharmaceuticals Inc., Trust for the Benefit of Members of the Raymond Sackler Family, and The P.F. Laboratories, Inc.

[8] The same definitions and exclusions found in the General Class Definition, *supra*, shall apply to these alternative subclasses.

[9] Defined in the "Pharmaceutical Marketing and Manufacturer Defendants" section, *infra*.

[10] Defined in the "Pharmaceutical Marketing and Manufacturer Defendants" section, *infra*.

whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Mallinckrodt Defendants;"[11]

d. Tennessee residents born after March 21, 2000, who were medically diagnosed as being exposed in utero to opioids, who were pharmacologically weaned from opioids and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Actavis Defendants;"[12]

e. Tennessee residents born after March 21, 2000, who were medically diagnosed as being exposed in utero to opioids, who were pharmacologically weaned from opioids and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Janssen Defendants;"[13]

f. Tennessee residents born after March 21, 2000, who were medically diagnosed as being exposed in utero to opioids, who were pharmacologically weaned from opioids and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the Defendants or by the non-Defendant co-conspirator Purdue.

g. Tennessee residents born after March 21, 2000, who were medically diagnosed as being

[11] Defined in the "Pharmaceutical Marketing and Manufacturer Defendants" section, *infra.*

[12] Defined in the "Pharmaceutical Marketing and Manufacturer Defendants" section, *infra.*

[13] Defined in the "Pharmaceutical Marketing and Manufacturer Defendants" section, *infra.*

exposed in utero to opioids, who were pharmacologically weaned from opioids and whose birth mother received and/or filled a prescription for opioids or opiates in the ten months prior to the birth of the infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant and/or by unnamed, co-conspirator Purdue.

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

280. 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' misrepresentations, activities, 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 Putative 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 Putative Class Members. Plaintiffs' interests are identical to and aligned with those of other Putative Class Members. Plaintiffs and the Putative 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.

281. Rule 23(b)(1)(B) authorizes certification when "prosecuting separate actions by or against individual class members would create a risk of ... adjudications with respect to individual class members that, as a practical matter, would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests."

282. Rule 23(b)(1)(B) is applicable in so-called "limited fund" cases like this one.

283. 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.

284. 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 has significant value for Rule 23(b)(2) Class Members because such detection will help Class Members monitor and minimize the harm therefrom. Due to neonatal opioid exposure of the Rule 23(b)(2) Class Members, surveillance in the form of periodic medical examinations is reasonable and necessary, because such surveillance will provide early detection and diagnosis of NAS and its effects. As a remedy for the negligent and unconscionable conduct alleged in this Second Amended Complaint, Defendants should be required to fund a medical monitoring and surveillance 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.

285. Plaintiff does not assert negligence, gross negligence or any claim for compensatory money damages as an issue for class-wide treatment.

CLASS-WIDE CAUSES OF ACTION
CLASS COUNT I – PUBLIC NUISANCE

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

287. Defendants substantially participated in public nuisance-causing activities.

288. The public nuisance is the over-saturation of opioids in Tennessee creating the opioid crisis and the adverse social, economic, and human health outcomes associated with widespread opioid use, which led to the increasing incidence of NAS.

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

290. Defendants' public 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.

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

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

a. Has harmed and will continue to harm NAS-affected children;

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

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

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

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

294. 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.

295. Defendants' public 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 Pharmaceutical Defendants dissemination of false "scientific" facts and advice.

296. 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. The Pharmaceutical Defendants flooded the distribution channels and the geographic and demographic area of Tennessee with opioid pills. Distributor Defendants had the power to shut off the supply of illicit opioids to patients and consumers of Tennessee, yet they did the opposite by flooding the U.S. (including Tennessee) with opioid pills.

297. This Court has found that a reasonable jury could conclude that evidence of rising instances of NAS and overdose, as well as the growing need for foster care placements for children who lost parents to overdose or incarceration, were an unreasonable interference with a right common to the general public, constituting a nuisance. *See* Opinion and Order Denying Manufacturer Defendants' Motion for Summary Judgment on Plaintiffs' Public Nuisance Claims, Case 1:17-md-02804-DAP, Doc #2578, filed 09/09/2019.

298. Plaintiffs and the Class also have suffered unique harms and special damages different from the public at large, namely, that they personally suffered NAS.

299. As a direct and proximate result of the public nuisance, Plaintiffs and the Class have incurred special legal damage, born a great burden, and suffered the irreparable harm of living with increased risk of serious latent disease.

300. 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.

301. Defendants should be required to pay the expenses Plaintiffs and the Class and their communities have incurred or will incur to fully abate the nuisance, and Defendants should be ordered to carry out the injunctive relief claimed below.

CLASS COUNT II – TENNESSEE DRUG DEALER LIABILITY ACT
Tenn. Code Ann.§ 29-38-101, *et seq.*

302. Tennessee's Drug Dealer Liability Act ("DDLA"), Tenn. Code Ann. § 29-38-101, et seq., provides a civil remedy for "damages to persons in a community as a result of illegal drug use." Tenn. Code Ann. § 29-38-102.

1. Among the persons to whom the DDLA provides a remedy are "infants injured as a result of exposure to drugs in utero." Tenn. Code Ann. § 29-38-102.

2. The Tennessee General Assembly has codified its deep concern for infants exposed to drugs, stating that "[d]rug babies, who are clearly the most innocent and vulnerable of those affected by illegal drug use, are often the most physically and mentally damaged due to the existence of an illegal drug market in a community. For many of these babies, the only hope is extensive medical and psychological treatment, physical therapy, and special education. All of these potential remedies are expensive. These babies, through their legal guardians and through court appointed guardians ad litem, should be able to recover damages from those in the community who have

entered and participated in the marketing of types of illegal drugs that have caused their injuries." Tenn. Code Ann. § 29-38-103(7).

3. The mothers of Baby K.L.F. and Baby C.W. made unlawful purchases of drugs produced and distributed by Defendants in Tennessee.

4. During both the time in which their mothers developed an addiction to opioids and while pregnant with Baby K.L.F. and Baby C.W., Defendants directed their opioids to the Tennessee market.

5. Baby Plaintiffs were born with NAS as a result of their exposure in utero to illegal opioid drugs. This drug exposure provides them the right to sue for damages under the DDLA. Tenn. Code Ann.§ 29-38-106(a)(2).

6. Baby K.L.F. brings this action by and through her adoptive parents Darren and Elena Flanagan. Baby C.W. brings this action by and through his adoptive parents Sharon A. Walker and David S. Walker. Legal Guardians of children exposed to illegal drugs in utero are authorized to bring this action under the DDLA. Tenn. Code Ann.§ 29-38-106(a)(l).

7. The DDLA makes anyone who "knowingly participates in the illegal drug market within this state ... liable for civil damages." Tenn. Code Ann. § 29-38-105(a).

8. "A person may recover damages under [the DDLA] ... for injury resulting from an individual's use of an illegal drug." Tenn. Code Ann.§ 29-38-105(b).

9. Under Tennessee criminal laws, such as Tenn. Code Ann§ 39-17-417 and Tenn. Code Ann § 39-17-418, heroin and other opioids are illegal drugs if possessed, sold, and distributed without a valid prescription.

10. For purposes of the DDLA, an "'individual drug user' means the individual whose illegal drug use is the basis of an action brought under [that statute]," Tenn. Code Ann. § 29-38-104(4).

11. The mothers of Baby K.L.F. and Baby C.W. were "individual drug user[s]" who acquired prescription drugs and heroin during their pregnancies from local unlicensed drug dealers.

12. The purchases by the mothers of Baby K.L.F. and Baby C.W. of various prescription opioids and heroin were illegal in that they were made without a valid prescription as required by Tenn. Code Ann.§ 53-11-308(a).

13. The DDLA imposes liability on those who directly participate in the distribution of an illegal drug that causes damages. Damages may be recovered under the DDLA from a "person who knowingly distributed, or knowingly participated in the chain of distribution of, an illegal drug that was actually used by the individual drug user." Tenn. Code Ann. § 29-38-106(5)(b)(1).

14. The DDLA also imposes market liability on those who participate in the unlawful distribution of drugs in the area where illegal drugs cause damages. Damages may be recovered under the DDLA from a "person who knowingly participated in the illegal drug market, if (A) [t]he place of illegal drug activity by the individual drug user is within the illegal drug market target community of the defendant; (B) [t]he defendant's participation in the illegal drug market was connected with the same type of illegal drug used by the individual drug user; and (C) [t]he defendant participated in the illegal drug market at any time during the individual user's period of illegal drug use." Tenn. Code Ann. § 29-38-106(b)(2)(A)-(C).

15. Defendants knowingly participated in the manufacture and/or distribution of prescription opioids that reached Tennessee during all times relevant to this complaint. For purposes

of the DDLA, Defendants' "illegal drug market target community" is the entire state of Tennessee, because Defendants participated in the illegal drug market by distributing 4 ounces or more of a "specified illegal drug." Tenn. Code Ann§§ 29-38-104(8), 29-38-109(4). As noted by the Tennessee Department of Health in a 2015 presentation, the Tennessee market for hydrocodone and oxycodone pills comprised of 51 hydrocodone pills and 113.5 oxycodone pills for every Tennessean. Commissioner of Health Dreyzehner noted that 50% of mothers of NAS babies obtained their pills, in whole or in part, from diverted pills (28.7% solely from diverted drugs). Given that a single oxycodone tablet, on information and belief, weighs approximately 135 mg and contains at least 10 mg of opioid, there can be no question that each of the Pharmaceutical Defendants far exceeded the four ounce level.

16. The Defendants knowingly failed to implement effective controls and procedures in their supply chains to guard against theft, diversion, and abuse of prescription opioids, and failed to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

17. As a result, Defendants knowingly disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including "pill mills."

18. The Defendants also enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including "pill mills" as well as other drug dealers, knowing that such opioids would be illegally trafficked and abused.

19. During pregnancy, the mothers of Baby K.L.F. and Baby C.W. illegally bought opioids and consumed the opioids within Tennessee state house legislative districts. Under the

DDLA, those legislative districts are "place[s] of illegal drug activity." Tenn. Code Ann.§ 29-38-104(11).

20. Having illegally distributed opioids during the mothers' pregnancies, Defendants are liable to Plaintiffs under the DDLA for damages caused by opioids that were acquired from distribution channels in which Defendants were a market participant.

CLASS COUNT III - CIVIL CONSPIRACY

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

22. All Defendants acted in concert to mislead medical professionals, patients, the scientific community, the CDC, the FDA, the DEA, and the general public about the addictive nature of opioids and the risk of serious latent disease associated with in utero exposure to opioids so that their profits would increase.

23. The Pharmaceutical Defendants continuously supplied prescription opioids to the Distributor Defendants, despite having actual or constructive knowledge that said Distributor Defendants 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.

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

25. 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.

26. 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.

27. This Court has found that there is a genuine issue of material fact as to whether the Pharmaceutical Defendants had an agreement to commit an unlawful act, among themselves or with other Defendants in order to expand the market for prescription opioids, and that a reasonable jury could review the evidence presented and find that Distributor Defendants shared a general conspiratorial objective with themselves and other Defendants to expand the opioid market and disregard regulatory obligations in order to achieve that goal. *See* Order Regarding Defendants' Summary Judgment Motions on Civil Conspiracy Claims, Case 1:17-md-02804-DAP, Doc #2562, Filed 09/03/2019.

28. As a result of the concerted actions between and among Defendants, Plaintiffs and the Class have suffered and are entitled to relief.

CLASS COUNT IV – INJUNCTIVE AND EQUITABLE RELIEF OF MEDICAL MONITORING AND MEASURES TO PROTECT THE CLASS FROM IRREPARABLE HARM

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

30. By definition, Plaintiffs 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.

31. Plaintiffs and the Class face a lifetime of latent, dread medical and emotional conditions proven to be linked to in utero exposure to 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.

32. Plaintiffs 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.

33. Plaintiffs and the Class will benefit from a medical monitoring program featuring an epidemiological component that collects and analyzes medical monitoring results so that other heretofore unrecognized latent, dread diseases that may be associated with in utero exposure may be identified and treating professionals may better care for the Class Members, and so that medical professionals engaged in the research and development of new treatment will have access to a broader universe of data.

34. Further, Plaintiffs 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.

35. The harm visited upon Plaintiffs and the Class is irreparable.

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

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

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

39. Plaintiffs and the Class also seek injunctive relief, including enjoining 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 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.

40. In addition to medical monitoring, Plaintiffs, on behalf of the Class, seek the following injunctive relief aimed at changing the standard of care for those born exposed to opioids in utero (to prevent them from becoming addicted to opioids) and spreading information upon the

record so that medical science has a better understanding of the potential negative health impacts of exposure to opioids in utero:

a. Order Defendants to seek FDA approval of labeling, warnings, and package inserts changing the standard of care to discourage the prescription of opioids for dental surgery performed on minors.

b. Order Defendants to seek FDA approval of labeling, warnings, and package inserts changing the standard of care to discourage the prescription of opioids to patients who were exposed to opioids in utero.

c. Order Defendants to immediately spread upon the public record all scientific and medical studies, data, experiments, white papers, research, or other materials relating to synthetic opioids, regardless of whether such material had ever been provided to the FDA or whether Defendants assert trade secret protection.

INDIVIDUAL CAUSES OF ACTION

INDIVIDUAL COUNT I – NEGLIGENCE

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

42. Defendants owe a non-delegable duty to Plaintiffs to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

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

44. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of Plaintiffs.

45. Defendants' behavior caused a substantial injury and damage to Plaintiffs.

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

a. Consciously supplying the market in Tennessee 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.

47. 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.

48. 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; (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.

49. 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.

50. 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.

51. 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.

52. 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. That duty cannot be delegated to another party.

53. Plaintiffs are without fault, and the injuries to Plaintiffs would not have happened in the ordinary course of events if Defendants had used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

54. The aforementioned conduct proximately caused damage to Plaintiffs.

INDIVIDUAL COUNT II – PUNITIVE DAMAGES

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

56. 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 are thus entitled to recover punitive damages against Defendants.

57. 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.

58. 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.

59. 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.

60. An award of punitive and exemplary damages is necessary to punish Defendants, and each of them, and to deter any reoccurrence of the intolerable conduct described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Putative Class Representatives Sharon and David Walker, as the next friend and guardian of Baby C.W., individually and on behalf of all others similarly situated, and Individual Plaintiffs Darren and Elena Flanagan, as the next friend and guardian of Baby K.L.M., request that the Court grant the following relief:

a. Class-wide injunctive and equitable relief of medical monitoring and continuing treatment;

b. Class-wide injunctive relief, including enjoining 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 requiring them to abide by the Controlled Substances Act, provide the required control measures, and prevent unauthorized users from obtaining opioids;

c. Class-wide injunctive relief modifying the standard of care for treating NAS babies;

d. Class-wide injunctive relief requiring defendants' to spread upon the public record all confidential medical and scientific information regarding opioids;

e. Non-class individual compensatory damages for personal injury, medical costs, pain and suffering, treatment, future treatment costs, lost wages and all other damages;

f. Non-class individual punitive damages;

g. Attorneys' fees and costs;

h. Pre- and post-judgment interest;

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

j. A trial by jury for all counts so triable.

DATED: October 8, 2019 Respectfully submitted by:

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of October, 2019, a copy of the above and foregoing has been electronically filed with the Clerk of Court using the CM/ECF system, which provides an electronic service notification to all counsel of record registered as CM/ECF users.

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