IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

DARREN AND ELENA FLANAGAN,
INDIVIDUALLY AND AS ADOPTIVE PARENTS
AND NEXT FRIENDS OF BABY K.L.F.,
ON BEHALF OF THEMSELVES
AND ALL OTHERS SIMILARLY SITUATED,

Plaintiffs,

v.

CASE NO. 2:18-cv-02194

CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED

PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
MCKESSON CORPORATION;
CARDINAL HEALTH, INC.;
AMERISOURCEBERGEN CORPORATION;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS LLC; and
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,

Defendants.

CLASS ACTION COMPLAINT

NOW COME Plaintiffs and Putative Class Representatives Darren and Elena Flanagan, as the adoptive parents and next friends of Baby K.L.F., individually and on behalf of all other

similarly situated, hereby filing their Complaint against the Defendants for damages, equitable, statutory, and injunctive relief. In support thereof, Plaintiffs state as follows:

INTRODUCTION

1. Like thousands of children born every year, Baby K.L.F. was born addicted to opioids. Prenatal exposure to opioids cause severe withdrawal symptoms and lasting developmental impacts. Baby K.L.F. was born two years ago. The first days of Baby K.L.F.'s life were spent in excruciating pain as doctors weaned the infant from opioid addiction. Baby K.L.F. will require years of treatment and counseling to deal with the effects of prenatal exposure. Baby K.L.F. and her mother 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 K.L.F. was diagnosed with Neonatal Abstinence Syndrome ("NAS"), a condition suffered by babies of mothers addicted to opioids. Baby K.L.F. was forced to endure a painful start to her life; crying excessively, arching her back, refusing to feed, and shaking. NAS is a clinical diagnosis, and "a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy."[1] Baby K.L.F. spent her first days in a Neonatal Intensive Care Unit writhing in agony as she went through detoxification, going to on spend five weeks there.

3. Upon information and belief, Baby K.L.F.'s mother was prescribed to Defendants' opioids and her addiction began prior to K.L.F.'s gestation. K.L.F.'s mother resided and purchased these opioids in Tennessee.

4. Upon information and belief, K.L.F.'s mother consumed opioids manufactured

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

and distributed by all named defendants including:

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

b. Cephalon's products Actiq and Fentora;

c. Janssen's product Duragesic;

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

e. Activis' product Norco and Kadian.

5. Baby K.L.F.'s experience is part of an opioid epidemic sweeping through the United States, including Tennessee, that has caused thousands of infants great suffering and continuing developmental issues. This epidemic is the largest health care crisis in U.S. history. Plaintiffs bring this class action to eliminate the hazard to public health and safety caused by the opioid epidemic and to abate the nuisance caused by Defendants' false, negligent and unfair marketing and/or unlawful diversion of prescription opioids. Plaintiffs further seek the equitable relief of medical monitoring to provide this class of infants the monitoring of developmental issues that will almost inevitably appear as they grow older and equitable relief in the form of funding for services and treatment.

6. The incidence of NAS has been increasing in the United States. The Substance Abuse Mental Health Services Administration reported that 1.1% of pregnant women abused opioids (0.9% used opioid pain relievers and 0.2% used heroin) in 2011.[2]

7. In recent years, there has been a dramatic rise in the proportion of infants who have been exposed to opioids. Opioid use among women who gave birth increased in the United States from 1.19 to 5.63 per 1,000 hospital births per year between 2000 and 2009. Concurrently the incidence of neonatal abstinence syndrome (NAS) among newborns during the same period

[2] *Id.*

(from 1.20 per 1,000 hospital births per year in 2000 to 3.39 per 1,000 hospital births per year in 2009).[3]

8. In a study from Florida, the number of newborns who had NAS and were admitted to the NICU increased by 10-fold from 2005 to 2011. Increases in the incidence of NAS have been reported uniformly across community hospitals, teaching hospitals, and children's hospitals.[4]

9. The incidence of NAS in newborns born to opioid-dependent women is between 70 and 95 percent. Research suggests that newborns with NAS (most commonly associated of opioid misuse during pregnancy) are more likely than all other hospital births to have low birthweight or respiratory complications. Untreated heroin and other opioid misuse during pregnancy also is associated with increased risk of placental abruption, preterm labor, maternal obstetric complications, and fetal death.[5]

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

11. 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,

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

[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.

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

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.

12. 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.

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

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

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

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

PARTIES

A. Plaintiffs

16. Baby K.L.F. and Putative Class members are individuals who have suffered Neonatal Abstinence Syndrome as a result of exposure to opioids in utero. This drug exposure provides Baby K.L.F. the right to sue, through her next friend and guardian, for damages under product liability, nuisance, negligence, and gross negligence.

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

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

B. Defendants

19. 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.

20. 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.

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

22. McKesson, Cardinal, and AmerisourceBergen are collectively referred to hereinafter as "Distributor Defendants."

23. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and Tennessee. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

24. 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.

25. 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.

26. 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, Inc., 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.")

27. 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. 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.

28. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly- owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. hereinafter are collectively referred to as "Endo.") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and 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.

29. 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.

30. Purdue, Cephalon, Janssen, Endo, and Actavis are collectively referred to hereinafter as the "Pharmaceutical Defendants."

JURISDICTION AND VENUE

31. Jurisdiction of this Court arises under the laws of the United States 28 U.S.C. § 1332(a), as the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of attorney's fees and costs.

32. This Court is also 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, a citizen of the State of Florida, and Defendants. The proposed class exceeds 100 persons. Further, the amount in controversy exceeds $5,000,000.00.

33. Defendants have engaged in conduct and activities over a long time, systematically, individually, jointly, and severally, in Tennessee that have caused all of the damages of Plaintiffs, Baby K.L.F. and the Class, all of which form the bases of the causes of action in this Complaint as against Defendants. Defendants have committed multiple torts and breaches within the State of Tennessee, repeatedly and systematically.

34. Defendants, for a long time, repeatedly and systematically, have substantial contacts and business relationships within Tennessee and its patients and citizens, including consensual relationships and contracts performed within Tennessee, some or all of which form the basis of the causes of action in this Complaint as against Defendants.

35. 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. All causes of action herein relate to Defendants' wrongful actions, conduct, and omissions committed against Plaintiffs and the Class, and the consequences and damages related to said wrongful actions, conduct, and omissions.

36. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events giving rise to the claims occurred in the Western District of Tennessee.

BACKGROUND FACTS

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

38. 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."

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

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

PHARMACEUTICAL DEFENDANTS' WRONGFUL CONDUCT

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

prescribers and vulnerable patient populations, including those in Tennessee.

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

43. The Pharmaceutical Defendants' direct and branded ads negligently portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue ran a series of ads, called "Pain Vignettes," for OxyContin that featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

44. 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.

45. The FDA has cited at least one of these Defendants for negligent promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that

"[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

46. The Pharmaceutical Defendants invited doctors to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by these Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

47. 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.

48. 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.

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

50. 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.

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

52. 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.

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

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

55. 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 conveying negligent misrepresentations to those doctors and patients about the risks and benefits of long-term opioid use, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

56. To convince doctors and patients that opioids are safe, the Pharmaceutical Defendants negligently trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (a) starting patients on opioids was low- risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

57. The Pharmaceutical Defendants negligently claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these negligent misrepresentations by opioid manufacturers are: (a) Actavis employed a patient education brochure that negligently claimed opioid addiction is "less likely if you have never had an addiction problem;" (b) Cephalon and Purdue sponsored

APF's Treatment Options: A Guide for People Living with Pain, negligently claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which negligently claimed that "[p]eople who take opioids as prescribed usually do not become addicted;" (d) Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "most people do not develop an addiction problem;" (e) Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as "myth" the claim that opioids are addictive; (f) a Janssen website negligently claimed that concerns about opioid addiction are "overestimated;" (g) Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management – that negligently claims that pain is undertreated due to "misconceptions about opioid addiction."

58. 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."

59. 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]."

60. 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.

61. The Pharmaceutical Defendants negligently instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudo-addiction" – a term used by Dr. David Haddox, who went to work for Purdue, and Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue. Defendants negligently claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these negligent claims are: (a) Cephalon and Purdue sponsored Responsible Opioid Prescribing, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one

doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated;" (c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudo-addiction by teaching that a patient's aberrant behavior was the result of untreated pain; (d) Purdue sponsored a negligent CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse in which a narrator notes that because of pseudo-addiction, a doctor should not assume the patient is addicted.

62. 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."

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

Opioid Use: Balancing the Need and Risk, claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths;" (c) Purdue represented in scientific conferences that "bad apple" patients – and not opioids – were the source of the addiction crisis, when in fact the "bad apples" were the Defendants.

64. 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."

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

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

67. 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."

68. The Pharmaceutical Defendants negligently claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences, and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example: (a) an Actavis patient brochure stated - "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not

addiction;" (b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, claiming that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain; (c) an Endo website, painknowledge.com, claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain;" (d) an Endo pamphlet Understanding Your Pain: Taking Oral Opioid Analgesics, stated "The dose can be increased. . . . You won't 'run out' of pain relief;" (e) a Janssen patient education guide Finding Relief: Pain Management for Older Adults listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages; (f) Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will; (g) Purdue's A Policymaker's Guide to Understanding Pain & Its Management stated that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages; (h) a Purdue CME entitled Overview of Management Options taught that NSAIDs and other drugs, but not opioids, were unsafe at high dosages; (i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

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

"avoid increasing dosages" above 90 morphine milligram equivalents per day.

70. 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."

71. 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.

72. 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.

73. 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."

74. These numerous, longstanding misrepresentations minimizing the risks of long-term opioid use persuaded doctors and patients to discount or ignore the true risks. Pharmaceutical Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants negligently and misleadingly touted the benefits of long-term opioid use and negligently and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and negligent claims, they continue to make them today.

75. For example, the Pharmaceutical Defendants negligently claimed that long-term opioid use improved patients' function and quality of life, including the following misrepresentations: (a) an Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives; (b) an Endo advertisement that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks, portraying

seemingly healthy, unimpaired persons; (c) a Janssen patient education guide Finding Relief: Pain Management for Older Adults stated as "a fact" that "opioids may make it easier for people to live normally" such as sleeping peacefully, working, recreation, sex, walking, and climbing stairs; (d) Purdue advertisements of OxyContin entitled "Pain vignettes" implied that OxyContin improves patients' function; (e) Responsible Opioid Prescribing, by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function; (f) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain counseling patients that opioids "give [pain patients] a quality of life we deserve;" (g) Endo's NIPC website painknowledge.com claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse;" (h) Endo CMEs titled Persistent Pain in the Older Patient claimed that chronic opioid therapy had been "shown to reduce pain and improve depressive symptoms and cognitive functioning;" (i) Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function;" (j) Purdue's A Policymaker's Guide to Understanding Pain & Its Management claimed that "multiple clinical studies" had shown opioids as effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients; (k) Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

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

conclusion throughout its 2016 Guideline:

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

77. 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.

78. The 2016 CDC Guideline was not the first time a federal agency repudiated the Pharmaceutical Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." In 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

79. The Pharmaceutical Defendants also negligently and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by

Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." The 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

80. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all relevant times. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and negligent, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

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

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

83. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain; (b) Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) in December 2011, Cephalon widely disseminated a journal supplement

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

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

85. Purdue unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

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

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

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

89. The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned these Defendants of this, and these Defendants had access to scientific studies, detailed prescription data, and reports of adverse events,

including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

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

91. The Pharmaceutical Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, fake independent groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Pharmaceutical Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

92. 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.

93. Thus, the Pharmaceutical Defendants successfully concealed from the medical community, municipalities, patients, and health care payers facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert. Plaintiffs did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

94. 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.

95. The Pharmaceutical Defendants' 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 these Defendants' negligent marketing scheme, these doctors would not have prescribed as many opioids. These Defendants' negligent marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' negligent marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and

those patients using opioids would be using less of them.

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

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

98. 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."

99. 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.

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

DISTRIBUTOR DEFENDANTS' WRONGFUL CONDUCT

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

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

103. 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.

104. 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.

105. 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.

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

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

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

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

110. 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.

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

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

113. 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.

114. 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.

115. All opioid distributors are required to maintain effective controls against opioid

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

116. 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.

117. 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.

118. 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.

119. To maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR § 1301.71.

120. 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.

121. 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.

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

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

124. 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.

125. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

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

127. 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."

128. 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.

129. 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).

130. 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."

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

132. 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.

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

Controlled Substances Act.

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

135. 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.

136. 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."

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

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

139. 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.

140. 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.

141. 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).

142. 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.

143. 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.

144. 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.

145. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the consumer market of Tennessee and in the geographic area served by its hospitals with highly-addictive opioids would allow opioids to fall into the hands of children, addicts,

criminals, and other unintended users.

146. 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.

147. 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.

148. 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.

149. 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.

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

151. 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.

152. 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.

CLASS ACTION ALLEGATIONS

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

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

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

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

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

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

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

c. Plaintiffs' claims are typical of the class. Plaintiffs' injuries are typical of

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

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

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

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

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

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

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

159. Defendants' conduct presents predominant common factual questions. This class is bound together by the common factual questions relating to whether the Defendants' tortious

activities led to physicians over-subscription of opioids and created a diversionary market for opioids thus certification is proper under Rule 23 (c)(4). Regardless of whether Plaintiffs and the Class Members are presenting individualized damages such as pain & suffering, they will present common liability proof that is the same for each member of the Class. Across claim categories, Plaintiffs' common proof of Defendants' liability will involve the same cast of characters, events, discovery, documents, fact witnesses, and experts.

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

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

judicial economy, the rights of each member of the class or subclasses, should that be determined to be appropriate.

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

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

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

169. 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.

170. As a result of Defendants' negligent conduct, the Rule 23(b)(2) Class Members are at increased risk of NAS and developmental issues. Early detection of neonatal exposure and developmental issues through examination and testing, with treatment as necessary, has significant value for Rule 23(b)(2) Class Members because such detection will help Class Members monitor, minimize and treat the harm therefrom. Due to neonatal opioid exposure by the Rule 23(b)(2) Class Members, surveillance, surveillance in the form of periodic medical

examinations and treatment is reasonable and necessary, because such surveillance will provide early detection, diagnosis and treatment of NAS and its effects. As a remedy for the negligent and unconscionable conduct alleged in this Complaint, Defendants should be required to fund a medical monitoring and treatment program designed to identify and combat NAS and its effects on the Class and provide desperately needed neonatal care and treatment programs as NAS affected children develop.

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

CAUSES OF ACTION

COUNT I - NUISANCE

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

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

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

175. Defendants' 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, people at risk of overdose, and criminals.

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

detect, halt and report suspicious orders of controlled substances.

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

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

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

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

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

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

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

180. 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.

181. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Manufacturer

Defendants dissemination of false "scientific" facts and advice.

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

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

184. Plaintiff Baby K.L.F. and the Class also have suffered unique harms different from the public at large, namely, that they personally suffer NAS.

185. 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.

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

COUNT II - NEGLIGENCE AND GROSS NEGLIGENCE

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

188. Defendants owe a non-delegable duty to Plaintiff Baby K.L.F. and the Class to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

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

190. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of Baby K.L.F. and the Class.

191. Defendants' behavior caused a substantial injury and damage to Baby K.L.F. and the Class.

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

a. Consciously supplying the market in the 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.

193. 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.

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

195. 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.

196. 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.

197. 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.

198. Defendants are in a limited class of registrants authorized to legally distribute controlled substances. This places Defendants in a position of great trust and responsibility vis-a-vis Plaintiffs and the Class. Defendants owe a special duty to Plaintiffs, Baby K.L.F. and the

Class. That duty cannot be delegated to another party.

199. Plaintiffs, Baby K.L.F. and the Class are without fault, and the injuries to Plaintiffs, Baby K.L.F. and the Class would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

200. The aforementioned conduct of Defendants proximately caused damage to Plaintiffs, Baby K.L.F. and the Class.

COUNT III – NEGLIGENCE PER SE

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

202. Defendants had a duty to exercise reasonable care, and comply with existing laws, in the design, research, manufacture, marketing, supply, promotion, packaging, sale, testing, and/or distribution of their opioid products into the stream of commerce.

203. Defendants failed to exercise ordinary care and failed to comply with existing laws in the design, research, manufacture, marketing, supply, promotion, packaging, sale, testing, quality assurance, quality control, and/or distribution of their opioid products into interstate commerce in that Defendants knew or should have known that using opioids created an unreasonable risk of dangerous addiction and NAS, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medication.

204. The laws violated by Defendants as described above were designed to protect Plaintiff and similarly situated persons and to protect against the risks and hazards that have

actualized in this case. Therefore, Defendants' conduct constitutes negligence per se.

COUNT IV - PERSONAL INJURY

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

206. Plaintiff Baby K.L.F. and all those similarly situated have by definition suffered personal injury as a related to in utero exposure to opioids resulting in a diagnosis of NAS.

207. Plaintiff Baby K.L.F. and all those similarly situated have incurred medical costs for the treatment of NAS including but not limited to physician's care, extended stay in the hospital after birth and drugs utilized to wean the infants from dependence upon opioids.

208. Plaintiff Baby K.L.F. and all those similarly situated have suffered the aforementioned personal injury of NAS due to the conduct and omissions of the Defendants.

209. Medical costs related to the treatment of NAS are readily calculable.

210. Plaintiff Baby K.L.F. and all those similarly situated seek class-wide damages for the reimbursement of medical costs associated with NAS.

211. Plaintiff Baby K.L.F. and all those similarly situated seek individual damages for pain & suffering, emotional distress, annoyance and inconvenience.

COUNT V - CIVIL CONSPIRACY

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

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

constructive knowledge that said pharmacies were habitually breaching their common law duties and violating the CSA.

214. 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.

215. 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.

216. 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.

217. As a result of the concerted actions between and among the Defendants, the Plaintiff and the class have suffered damages.

218. Plaintiffs, Baby K.L.F. and the Class demand judgment against each Defendant for compensatory damages.

COUNT VI - INJUNCTIVE AND EQUITABLE RELIEF

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

220. By definition, Baby K.L.F. was exposed to opioids, a known toxic substance, at a concentration higher than expected for the general population.

221. To obtain medical monitoring damage under Tennessee law, "it is sufficient for

the plaintiff to show by expert medical testimony that the plaintiffs have an increased risk of disease, which would warrant a reasonable physician to order monitoring." *Bandy v. Trigen-Biopower, Inc*., No. 3:02-CV-459, 2006 WL 5321815, at 5 (E.D. Tenn. May 5, 2006) (citing *Day v. NLO*, 851 F. Supp. 869, 881 (S.D. Ohio 1994)).

222. Baby K.L.F. and those similarly situated face a lifetime of latent, dread medical and emotional conditions proven to be linked to in utero exposure opioids including but not limited to: brain damage, muscular-skeletal developmental disorders, speech and language disorders, cognitive developmental disorders, psychiatric disorders, emotional development disorders, behavioral disorders and increased risk of addiction.

223. Plaintiff Baby K.L.F. and those similarly situated 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.

224. Baby K.L.F. and those similarly situated will benefit from a medical monitoring program featuring an epidemiological component that collects and analyzes medical monitoring results[6] so that other heretofore unrecognized latent, dread diseases that may be associated with in utero exposure may be identified so that treating professionals may better care for the Class Members and so that medical professionals engaged in the research and development of new treatment will have access to a broader universe of data.

225. Further, Baby K.L.F. and those similarly situated 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,

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

cognitive therapy and speech therapy.

226. The harm visited upon Baby K.L.F. and those similarly situated is irreparable.

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

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

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

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

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

COUNT VII - PRODUCTS LIABILITY UNDER THE TENNESSEE PRODUCTS LIABILITY ACT TENN. CODE ANN. § 29-28-101 *ET SEQ.*

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

herein.

233. The manufacturer or seller of a product is liable for injuries caused by the product if it is in a defective condition or unreasonably dangerous at the time it leaves the control of the manufacturer or seller. Tenn. Code Ann. § 29-28-105.

234. A "defective condition" is defined as "a condition of a product that renders it unsafe for normal or anticipatable handling and consumption." Tenn. Code Ann. § 29-28-102(6).

235. A product is "unreasonably dangerous" where "a product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition." Tenn. Code Ann. § 29-28-102(8).

236. The Tennessee Supreme Court has held that Act's definition of "unreasonable dangerous" includes two separate tests, one from the buyer's perspective and one from the manufacture's perspective: the "consumer expectation test" and the "prudent manufacture test." *See Tatham v. Bridgestone Americas Holding, Inc.*, 473 S.W.3d 734, 750 (Tenn. 2015) (citing *Ray by Holman v. BIC Corp*., 925 S.W.2d 527, 531 (Tenn. 1996)). The consumer expectation test assesses "whether the product's condition poses a danger beyond that expected by an ordinary consumer with reasonable knowledge." *Id.* (quoting *BIC Corp.*, 925 S.W.2d at 529). The prudent manufacturer test, on the other hand, assesses whether, given the imputed knowledge of the condition of the product, a prudent manufacturer would place such a product into the stream of commerce. *Id*.

237. With regard to drug manufacturers, the Tennessee Supreme Court has recognized

that drug manufacturers have a duty to exercise ordinary and reasonable care not to expose the public to an unreasonable risk of harm from the use of their products. *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428–29 (Tenn. 1994). "Manufacturers of prescription drugs, like the manufacturers of any other unavoidably dangerous product, have a duty to market and distribute their products in a way that minimizes the risk or danger. They may discharge their duty by distributing the drugs with proper directions and adequate warnings to those who foreseeably could be injured by the use of their products." *Id.* (citing Restatement (Second) of Torts, § 402A comment k (1965)).

238. A product liability action is expressly defined to include the failure to warn or disclose. Tenn. Code Ann. § 29-28-102(6).

239. Tennessee courts apply the "learned intermediary doctrine" to drug manufacturers. Under the "learned intermediary doctrine," makers of unavoidably unsafe products who have a duty to give warnings may reasonably rely on intermediaries to transmit their warnings and instructions. *Id.* at 429 (citing Restatement (Second) of Torts, § 388 comment n, (1965)). The *Pittman* court further described the application of this doctrine to drug manufacturers:

> Physicians are such intermediaries because of the pivotal role they play in the unique system used to distribute prescription drugs. Accordingly, a majority of jurisdictions now recognize that the manufacturer of an unavoidably unsafe prescription drug can discharge its duty to warn by providing the physician with adequate warnings of the risks associated with the use of its drug. However, physicians can be learned intermediaries only when they have received adequate warnings. Thus, the learned intermediary doctrine does not shield a drug manufacturer from liability for inadequate warnings to the physician.

Pittman, 890 S.W.2d 425 at 428–29 (citations omitted).

240. At all times material to this action, Defendants were engaged in the business of

the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of opioid products.

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

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

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

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

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

246. Defendants knew that opioids are too addictive and to debilitating for long-term use for chronic pain, barring exceptional circumstances. Defendants knew that the only safe uses for their product were end of life care, short term pain relief after surgery, and pain relief related to cancer. Defendants failed to warn Tennessee physicians, potential mothers and pregnant women of the dangers of using their product outside of these areas.

247. Defendants' products were unreasonably dangerous because of inadequate warning such that it would not have been put on the market by a reasonably prudent manufacturer or seller that knew of its dangerous condition.

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

249. The opioid product manufactured and/or supplied by Defendants were defective in design in that an alternative design exists that would prevent addiction, NAS and severe and permanent injury to pregnant women and their unborn children. The product was unreasonably dangerous in design such that it would not have been put on the market by a reasonably prudent manufacturer or seller that knew of its dangerous condition.

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

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

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

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

254. Therefore Defendants are liable for the damages caused to the Plaintiffs and the Class by their opioid products' unreasonably dangerous and defective design and inadequate

warnings of their opioids' addictive properties.

COUNT VIII – STRICT PRODUCTS LIABILITY

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

256. Defendants are strictly liable for the damages to Plaintiffs and the Class caused by the defective design and inadequate warnings detailed above.

COUNT IX - PUNITIVE DAMAGES

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

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

259. 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.

260. 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.

261. As a direct result of Defendants' deliberate disregard for the rights and safety of others, gross negligence, malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiffs, Plaintiffs

suffered the injuries and dangers stated above.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Putative Class Representatives Darren and Elena Flanagan, individually and on behalf of Baby K.L.F. and all those similarly situated requests that the Court grant the following relief:

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

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

required control measures, and prevent unauthorized users from obtaining opioids;

c. Compensatory damages;

d. Restitution;

e. Punitive damages;

f. Attorneys' fees and costs;

g. Pre and Post Judgment Interest;

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

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

Date: 03/21/2018

Respectfully submitted by:

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