

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

MDL No. 2804

This document relates to:

Master Docket No.
1:17-MD-02804-DAP

AMANDA HANLON,
INDIVIDUALLY AND
ON BEHALF OF ALL OTHERS
SIMILARLY SITUATED;

Hon. Judge Dan A. Polster

AMY GARDNER,
INDIVIDUALLY AND
ON BEHALF OF HER
MINOR DAUGHTER A.L.D.
AND ALL OTHERS
SIMILARLY SITUATED,

Plaintiffs,

v.

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

CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED

Defendants.

Case No. _____

**CLASS ACTION COMPLAINT
ALSO FOR PRELIMINARY AND PERMANENT INJUNCTION AND
DECLARATORY JUDGMENT**

NOW COME Plaintiffs and Putative Class Representatives Amanda Hanlon and Amy Gardner, individually and on behalf of all other similarly situated women capable of becoming pregnant, who state as follows:

1. Plaintiffs seek a Preliminary and Permanent Injunction, and request a prompt hearing on the Preliminary Injunction. Defendants were and are negligent, as detailed below, and are thus liable to Plaintiffs and the Class. Further, Preliminary and Permanent Injunctive Relief is appropriate and necessary to prevent future harm, as is Declaratory Relief.
2. There is a grave threat of irreparable harm to the public and the Plaintiffs if preliminary injunctive relief is not granted. Many victims of the Opioid Crisis are babies born with Neonatal Abstinence Syndrome (“NAS”),¹ a condition suffered by babies of mothers prescribed and/or addicted to opioids during pregnancy. Prenatal exposure to opioids causes severe withdrawal symptoms and lasting developmental impacts. The number of infants born suffering from Neonatal Abstinence Syndrome is staggering. The incidence of NAS in the United States grew five-fold between 2000 and 2012. Recent studies suggest that the babies born with NAS to date number in the hundreds of thousands. Currently, the best estimates are that a child with NAS is born every 15 minutes.
3. The primary purpose of this suit, the others in this MDL, and those pending in state courts, is to permanently abate the opioid epidemic. This suit also seeks an injunction to assist

¹ Sometimes also referred to in the literature as Neonatal Opioid Withdrawal Syndrome (“NOWS”) or Opioid Use Disorder (“OUD”).

abatement during the pendency of these actions by reducing the number of NAS births through the following methods: 1) requiring a negative pregnancy test before an opioid can be dispensed to a woman capable of becoming pregnant, 2) dispensing only a seven-day supply, and 3) if additional opioids are prescribed after seven days, requiring another negative pregnancy test before dispensing the prescription. This request is not unlike other programs established by drug manufacturers, distributors, pharmacies, and the FDA for drugs with teratogenic properties which successfully protect fetal development.

4. As set forth in the accompanying Memorandum in Support of Motion for Preliminary Injunction, being filed herewith, there is a high probability of success on the merits against the Defendants because most of the Defendants have admitted to engaging in the wrongful acts described below in criminal plea agreements, cease and desist agreements or settlement agreements with federal agencies or state law enforcement officials, and have paid criminal and civil fines and assessments, and settlement amounts for their wrongful conduct. Nevertheless, their conduct has not been deterred, the opioid crisis has not been resolved or abated, and more relief, supervised by the judicial system of the United States, is necessary to protect the American public, and the next generation, from the Defendants.

Plaintiffs

5. Amanda Hanlon, a New York citizen, has sued individually and in a representative capacity for a NAS baby in her care and custody, and she also sues here for preliminary and permanent injunction. Amanda came to know the birth mother who was addicted to prescription opioids while pregnant. Amanda understood the baby was at risk and that the birth mother was unable to care for the child. Amanda worked with CPS authorities before birth. She has had sole custody of the baby since discharge from the ICU; she cares for the

child along with her own children. She is capable of becoming pregnant and fears that what happened to the birth mother could happen to her.

6. Amy Gardner, a Louisiana citizen and resident of Jefferson Parish, is the mother her minor teenage daughter A.L.D. Amy and A.L.D are capable of becoming pregnant Amy fears for herself and her daughter should either become pregnant.

Defendants

7. 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 United States. 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).
8. 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 United States. 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.

9. 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.
10. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the United States. 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 the U.S., 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 the U.S., 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 the United States 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 the U.S. 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.”)

11. 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. 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., 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.

12. 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 Zydene, in the United States. 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., by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

13. 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. The combined company changed its name to Actavis, Inc. as of January 2013, and 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 the United States. 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 the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

14. Purdue, Cephalon, Janssen, Endo, and Actavis are collectively referred to hereinafter as “Defendants” or the “Pharmaceutical Defendants.”

Jurisdiction and Venue

15. This Court is vested with jurisdiction by virtue of the Class Action Fairness Act, 28 U.S.C. § 1332(d). Minimal diversity exists between named Plaintiffs of this putative class action, citizens of the States of New York and Louisiana, and Defendants. The proposed class exceeds 100 persons. Further, the amount in controversy exceeds \$5,000,000, as the value of the benefit to the Class will exceed \$5,000,000. The typical post birth hospital admission cost for one NAS baby is \$180,000 to \$250,000. Thus the admission costs of as few as 20 NAS babies may exceed \$5,000,000. Babies afflicted with NAS are born every 15 minutes.
16. This Court has personal jurisdiction over Defendants, each of which has committed torts, in part or in whole, within the State of Ohio, as alleged herein. Moreover, Defendants have substantial contacts and business dealings directly within Ohio by virtue of their distribution, dispensing, and sales of prescription opioids.
17. Venue is proper in this Court pursuant to this Court’s Case Management Order One (Doc. 232) allowing direct filing into these MDL proceedings. Plaintiff reserve the right to move for transfer at the conclusion of pretrial proceedings.
18. Per Case Management Order One, Plaintiff does not concede that Ohio law applies by directly filing in this MDL proceeding.

Neonatal Abstinence Syndrome

19. Many victims of the Opioid Crisis are babies born with Neonatal Abstinence Syndrome (“NAS”), a condition suffered by babies of mothers prescribed and/or addicted to opioids during pregnancy. Prenatal exposure to opioids cause severe withdrawal symptoms and lasting developmental impacts.
20. Anything a pregnant woman ingests or breathes is transmitted to her baby by the placenta, before the mother’s liver filters the blood. Some things cross the placenta with ease; included among them, are opioids. Opioids are lipid (fat) based and easily cross the placenta; they have an affinity for the developing brain structures which are also lipid based. Science has not (yet) determined the dosage and duration of opioid exposure that will result in NAS. Babies with in-utero opioid exposure are subject to addiction and brain and other organ insult.
21. It is suspected that NAS babies experience DNA changes at the cellular level, particularly in the tissues of the brain and nervous system, and may suffer lifelong afflictions as a result of maternal use of prescription opioid medications during gestation. These babies often require extensive care because they are likely to experience lifelong mental health problems, developmental impairment, and physical health limitations.
22. The costs associated with these children in first weaning them from their addiction and then evaluation and services related to their injuries are astronomical. These costs threaten the budgets of every family with such a child and every political subdivision in the country. The only realistic means of reducing the NAS and OUD births is prevention.
23. Recently, there has been a dramatic increase in the number of fetuses that have been exposed to opioids. Women are also victims of the opioid epidemic, and health care for

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

24. Women are more likely to be prescribed opioids than men. Women have a higher opioid plasma concentration (up to 25% more) than men on a body weight adjusted basis. This means that the drugs' effects, including the likelihood of addiction, are higher in women than men. The government reports that one third of all pregnant women in this country are prescribed opioids. A natural consequence of opioid use in pregnant women is the tragic increase in the number of children exposed in-utero to opioids. The incidence of children born in this country with a NAS or OUD diagnosis has surged to the point where we are at risk of a lost generation. The problems from in-utero exposure may not end with the baby. A study suggests that opioids modify genes that make addiction more likely in the baby and this modification may carry on generations forward.
25. The number of infants born suffering from this insidious condition is staggering. The incidence of NAS in the United States grew five-fold between 2000 and 2012. Currently, the best estimates are that a child with NAS is born every 15 minutes.
26. In 2011, The Substance Abuse Mental Health Services Administration reported that 1.1% of pregnant women abused opioids (0.9% used opioid pain relievers and 0.2% used heroin).
27. In 2014, the number of babies born drug-dependent had increased by 500 percent since 2000, and children being placed in foster care due in part to parental drug abuse are going up — now it is almost a third of all child removals.
28. Opioid exposure during pregnancy is also associated with increased risks and incidence of placental abruption, preterm labor, maternal obstetric complications, maternal mortality, and fetal death.

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

30. Specifically, children diagnosed with NAS exhibit:

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

31. While the pathophysiological mechanism of opioid withdrawal in neonates is currently not known, several factors can affect the accumulation of opioids in the fetus. Opiate drugs have low molecular weights, are water soluble, and are lipophilic substances; hence, they are easily transferable across the placenta to the fetus. It is known that the transmission of opioids across the placenta increases as gestation increases. It is also known that synthetic opiates cross the placenta more easily compared with semisynthetic opiates. The

combination of cocaine or heroin with methadone further increases the permeability of methadone across the placenta. Together, the ease with which these drugs can cross the blood-brain barrier of the fetus, and the prolonged half-life of these drugs in the fetus may worsen the withdrawal in infants. Neonatal abstinence syndrome is the end result of the sudden discontinuation of prolonged fetal exposure to opioids.

32. NAS babies' mothers often purchase and consume prescription opioids from one or more Defendants. Each minor child suffers, and will suffer, lifelong mental illness, mental impairment, and loss of mental capacity. The minor child's entire health, use of the child's body and mind, and life, including the minor child's ability to live normally, learn and work normally, enjoy relationships with others, and function as a valuable citizen, child, parent, income-earner, and person enjoying life, are compromised, and permanently impaired.
33. Plaintiff's experience is part of an opioid epidemic sweeping through the United States, causing thousands of infants great suffering and continuing developmental physical, medical, occupational, and psychological issues. This epidemic is reportedly the largest health care crisis in U.S. history. Plaintiffs bring this class action to eliminate the hazard to public health and safety caused by the opioid epidemic and to abate the nuisance caused by Defendants' false, negligent and unfair marketing and/or unlawful diversion of prescription opioids.
34. 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 the United States to become flooded with prescription opioids.

Defendants' Wrongful Conduct

35. Opioid means “opium – like” and the term includes all drugs derived in whole or in part from the opium poppy. 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.” 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).
36. 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.
37. 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.

38. The Pharmaceutical Defendants spread their false and negligent statements by marketing their branded opioids directly to doctors and patients. 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 the United States.
39. A result of the Defendants’ aggressive marketing campaigns to healthcare professionals was to change the medical understanding of opioids from strong respect of their addictive nature and judicious use to more liberal and expansive use based on what we now know was false information that these engineered drugs would not result in addiction. As a result, standards of care and practice concerning opioids changed and are continuing to change. Leading associations of healthcare professionals devoted to the care of women and children have announced practice guidelines covering opioids and pregnancy; caution is the guide. Medical standards of care concerning opioids are evolving and are not consistent nationwide. And, it is no understatement to say that the standards of care regarding opioid administration remain muddled as a result of defendants’ conduct.
40. The Pharmaceutical Defendants’ direct and branded ads negligently portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website

www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue ran a series of ads, called “Pain Vignettes,” for OxyContin that featured chronic pain patients and recommended OxyContin for each. One ad described a “54-year-old writer with osteoarthritis of the hands” and implied that OxyContin would help the writer work more effectively. While Endo and Purdue agreed in 2015-16 to stop these particularly misleading representations in New York, they continued to disseminate them around the United States.

41. 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.
42. 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.
43. 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.

44. The Pharmaceutical Defendants have had unified marketing plans and strategies from state to state. This unified approach ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.
45. The Pharmaceutical Defendants negligently marketed opioids in the United States through unbranded advertising that promoted opioid use generally, while remaining 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.
46. 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.
47. The Pharmaceutical Defendants' negligent unbranded marketing also contradicted their branded materials reviewed by the FDA.
48. 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.

49. 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”).
50. The Pharmaceutical Defendants collaborated, through the aforementioned organizations and groups, to spread negligent messages about the risks and benefits of long-term opioid therapy.
51. To convince doctors and patients 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.
52. 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.

53. 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. Defendants also failed to report to the FDA, physicians, healthcare providers and end users that prescription opioids subject fetuses to addiction and harm from in utero exposure as a result of teratogenic properties that cause injury to the brain and other organs (not unlike Accutane) and NAS. 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.”

54. 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.”

55. 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].”

56. 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.

57. 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.”
58. Defendants 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 \leq 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.

59. 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.

60. 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."

61. 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."
62. 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.
63. 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.

64. 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.
65. 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.

66. 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. 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.
67. 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.

68. 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.
69. 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.

70. As a part of their negligent marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations. 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.
71. 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 NAS, addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that children are suffering NAS 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.
72. 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.

73. 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.

74. 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.

75. 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.

76. 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.

77. The Pharmaceutical Defendants' negligent marketing scheme caused and continues to cause doctors to prescribe opioids to patients, including pregnant mothers, 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, including pregnant mothers, 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, those patients using opioids would be using less of them, and significantly fewer pregnant mothers would be unwittingly exposing their unborn children to opioids.

78. 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.

79. 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 United States. 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.”

80. In a 2016 report, 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.”

81. 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.

Cause of Action: Negligence

82. As set forth in paragraphs 1- 81, Defendants were and are negligent for failing to inform the FDA, physicians, healthcare providers, and end users of their opioid products of their teratogenic effects, including but not limited to fetal death, NAS, and brain and other organ damage.

83. Defendants’ conduct is ongoing and continuous and constitutes a continuing tort.

Class Allegations

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

All women in the United States capable of becoming pregnant.

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

86. 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:

87. 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.
- b. There are common issues of law and fact, particularly whether Defendants' and their agents' policies and procedures that encouraged the prescription of opioids to pregnant women despite knowing the dangers to their children.
- c. Plaintiffs' claims are typical of the class. 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.

88. 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.

89. A class action may be maintained under Federal Rule of Civil Procedure 23(b)(2), as Defendants' have acted or refused to act on grounds generally applicable to the class, so that final injunctive relief and corresponding declaratory relief is appropriate respecting the class as a whole. The entry of injunctive relief is appropriate.
90. Defendants' tortious activities led to physicians' over-subscription of opioids to pregnant women, contributing to a dramatic increase in the number of infants born with Neonatal Abstinence Syndrome (NAS). Plaintiffs will present common liability proof that is the same for each member of the Class. Plaintiffs' common proof of Defendants' liability will involve the same cast of characters, events, discovery, documents, fact witnesses, and experts.
91. 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.
92. As a result of Defendants' negligent conduct, the Rule 23(b)(2) Class Members are at increased risk of exposing their unborn children to NAS and developmental issues. Early detection of pregnancy through mandatory testing prior to the filling of opioid prescriptions has significant value for Rule 23(b)(2) Class Members because such detection will help Class Members prevent harm to their unborn children.

Injunctive Relief Sought

93. As detailed in Plaintiff's concurrently filed Motion for Preliminary Injunction, Plaintiff seeks a preliminary and permanent injunction to assist abatement by reducing the number of NAS births by requiring a negative pregnancy test before an opioid can be dispensed to a woman capable of becoming pregnant, dispensing only a seven-day supply, and if additional opioids are prescribed after seven days, that there be another negative pregnancy test before

dispensing the prescription. This request is not unlike other programs established by drug manufacturers, distributors, pharmacies, and the FDA for drugs with teratogenic properties which successfully protect fetal development.

94. The risk of in utero exposure to opioids is that once born he or she will suffer a life fraught with physical, social, educational, and other permanent disability. The potential for opioid induced genetic modification may endanger and diminish the quality of life for that family for generations to come. There is no cure for the opioid caused injuries. And, the risk of developing future addiction in these children is real as they were once addicted, and their mother was as well.
95. Plaintiff and the Class have been, and will continue to be, substantially and irreparably harmed by Defendants' unlawful and improper actions, for which there is no adequate remedy at law. Under the facts and circumstances of this case, the balance of the equities clearly favors Plaintiffs, and injunctive relief is in the public interest.
96. The only remedy the law allows for physical and mental injuries is monetary compensation to those already injured. Women often times do not appreciate that they are pregnant for weeks, by then, an unwitting mother has exposed her child to a strong potential of permanent harm. And she is also exposed to the risk of losing her addicted child to child protection services, her liberty, and anguish in the years ahead. This injunction will lessen, if not eliminate, this pathway of irreparable harm. This injunction is necessary to prevent future harm.

Declaratory Relief Sought

97. Plaintiffs further seek a declaratory judgement from the Court under Fed. R. Civ. Pro. 57 stating that prescription opioids have a teratogenic effect.

Prayer for Relief

WHEREFORE, Plaintiffs and Putative Class Representatives Amanda Hanlon and Amy Gardner, individually and on behalf of all those similarly situated, request that the Court grant the following relief:

- A. Preliminary and Permanent Injunctive Relief prohibiting Defendants from dispensing any opioid prescription to any woman capable of becoming pregnant without first receiving notice/proof of a negative pregnancy test, dispensing only a seven-day supply, and if additional opioids are prescribed after those seven days, that there be another negative pregnancy test before dispensing the prescription;
- B. Declaratory Judgement stating that opioids have a teratogenic effect;
- C. Attorneys' Fees and Costs;
- D. All such other relief this Court deems just and equitable under the circumstances.

Plaintiffs are entitled to and hereby request a jury trial on all issues.

Respectfully submitted,

/s/ Celeste Brustowicz

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