IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

LISA MARIE REED, individually and as natural guardian of B.R., her minor child,

Plaintiff,

v.

GLAXOSMITHKLINE, LLC,

Defendant.

CIVIL ACTION NO.: 3:15-CV-1463-J-20PDB

COMPLAINT AND JURY DEMAND

COMES NOW, Plaintiff, LISA MARIE REED, individually and as the natural guardian of her son, B.R., a minor, ("Plaintiffs"), who by and through the undersigned counsel hereby files this Complaint and Jury Demand against Defendant, GLAXOSMITHKLINE, LLC, ("GSK"), for compensatory damages, punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to B.R. as a result of her prenatal exposure to the prescription drug ondansetron, which was sold and marketed by Defendant under the name Zofran® ("Zofran"). In support of this Complaint, Plaintiff alleges the following:

BACKGROUND INFORMATION

1. GLAXOSMITHKLINE, LLC., was formed as a result of a $76 billion merger between Glaxo Wellcome, Inc. and SmithKline Beecham, Inc., in 2000. After this merger, GSK became one of the largest pharmaceutical companies in the world, with annual reported sales of over $45 billion in 2009.

2. GSK invented the drug ondansetron[1] in the early 1980's in England and obtained a United States patent for ondansetron in 1987 and a second United States patent in 1988, which gave GSK the exclusive right to market and sell ondansetron in the United States until December 2006.[2]

3. GSK marketed and sold ondansetron under the name Zofran and Zofran was approved by the United States Food and Drug Administration ("FDA") in 1991 and **has been approved by the FDA** for the following two specific uses **only**: 1) prevention of nausea and vomiting due to cancer therapy; and 2) prevention of post-operative nausea and vomiting.

4. **GSK has never applied for nor received approval by the FDA of Zofran for treatment of nausea and vomiting ("morning sickness") associated with pregnancy, or any other condition in pregnant women.**

5. The proper procedures for GSK to lawfully market Zofran as a treatment for morning sickness require GSK to perform clinical studies on humans, and then submit the data to the FDA for the FDA to evaluate and either approve or deny the proposed use of the drug. A pharmaceutical company must obtain this FDA approval first in order to lawfully market a drug for treatment in pregnant women.

6. Despite never receiving FDA approval to prescribe Zofran for the treatment of morning sickness in pregnant women or never performing any clinical testing on humans, GSK heavily marketed Zofran "off-label" as a safe and effective treatment for morning sickness, while knowing this representation was false.

[1] Ondansetron and Zofran are used interchangeably throughout this Complaint. Zofran is the name trademarked by GSK and the name of the drug is ondansetron. In other words, Zofran is ondansetron.

[2] Glaxo Wellcome, Inc. actually applied for the new drug application for Zofran because the application was submitted to the FDA before GlaxoSmithKline was formed by the merger of Glaxo Wellcome, Inc. and SmithKline Beecham, Inc. in 2000. The abbreviation "GSK" is used to refer collectively to GlaxoSmithKline LLC and these two predecessor corporations.

7. Doctors began prescribing Zofran for this unapproved use and Zofran **became the most frequently prescribed anti-nausea drug** among pregnant women in the United States. Just prior to GSK's exclusive patent lapsing in December of 2006, sales of Zofran reached $1.3 billion for the first nine months of 2006. At this time consumers were falsely led to believe by GSK's sales representatives that Zofran was completely safe and effective for treatment of morning sickness.

8. A fetus grows by receiving nourishment and nutrients that pass through the placenta from the mother to the fetus. However, it is medically accepted fact that toxins from certain drugs may also pass through the placenta and harm the fetus. Therefore, healthcare providers and pregnant women need to be able to make informed decisions based on accurate warnings and information from the drug manufacturer on which, if any, prescription drugs should be taken during pregnancy.

9. The use of Zofran by women who are pregnant significantly increases birth defects when the drug is taken in the first trimester.

10. GSK marketed and promoted Zofran as safe and effective for the off-label use of treating morning sickness while having actual knowledge that this representation was false. The drug went through no clinical trials and there was no data that supported the assertion that Zofran was safe and effective if taken during pregnancy. The result of GSK's nationwide fraudulent marketing campaign is that, currently (as of 2015), about 1 million pregnant women are prescribed Zofran for off-label treatment of morning sickness.

11. At all times, while marketing Zofran for the off label treatment of morning sickness, GSK had the duty to warn, eliminate, and minimize the risk of birth defects.

12. Zofran is a "Pregnancy Category B" drug, one classification below the safest possible classification, and the warning label on Zofran from 1993 until present in the United States reads:

> **"Pregnancy: Teratogenic Effects:** Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at I.V. doses up to 4mg/kg per day and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed."[34]

13. GSK is under a legal obligation to state in the "Indications and Usage" section of the drug label that there is a lack of evidence that Zofran is safe for use by pregnant women or update the labeling if positive evidence of human fetal risk is subsequently discovered from adverse reaction data or marketing experience or studies in humans.

14. Since Zofran has been on the market, GSK has never updated or changed the "Indications and Usage" section to indicate that Zofran is not safe for use by pregnant women. GSK was under an obligation from the FDA to update Zofran's warning label to reflect the significant risk of birth defects by down-grading Zofran's pregnancy category to either a Category D or a Category X designation; both categories warn the consumer that the drug can cause harm to the fetus when administered to a pregnant women.

15. The warning label for Zofran sold in Canada states, **"the safety of ondansetron for use in human pregnancy has not been established...use of ondansetron in pregnancy is not recommended."**

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[3] The FDA divides the pregnancy rating system into six categories; A, B, C, D, X, N. "Category A" drugs have undergone well-controlled studies and there are no risks to the fetus in the first trimester, these are the safest possible drugs. "Category D" and "Category X" drugs have produced positive evidence of fetal risk in animals and humans; and these are the riskiest drugs. "Category N" means the drug has not been classified by the FDA.

[4] The FDA recently promulgated a new rule declaring that, as of June 2015, the current "pregnancy category" drug warning system will no longer be used. Instead, pharmaceutical companies must summarize risks of using the drug during pregnancy, discuss data supporting that summary, describe other relevant information health care providers can rely upon when making prescribing decisions to pregnant women.

16. At all times from 1991 to 2011, GSK had the duty to warn, minimize, or eliminate the risks of birth defects.

17. GSK failed to warn Zofran consumers from 1991 to 2011, that taking Zofran during pregnancy could cause birth defects.

18. GSK failed to take actions to minimize the risk of birth defects caused by taking Zofran during pregnancy from 1991 to 2011.

19. GSK failed to take actions to eliminate risk of birth defects caused by taking Zofran during pregnancy from 1991 to 2011.

20. At all relevant times, GSK never possessed any scientific research to support their marketing assertions that Zofran did not present an "unreasonable risk of harm" to developing fetuses.

21. August 27, 2013, Danish researchers revealed the results of their study in which Zofran significantly increases the risk of birth defects. Researchers analyzed all births in Denmark from 1997 to 2010 and studied those who took ondansetron in the first trimester.[5] Babies exposed to ondansetron were **2.1 times more likely** to have atrial septal defects, **2.3 times more likely** to have ventricular septal defects, and **4.8 times more likely** to have atrioventricular defects.[6]

[5] The accepted opinion in the medical community is that ondansetron only increases birth defects when taken in the first trimester. This Danish study was a response to an earlier Danish study which showed no risks of birth defects; however the study was flawed because most of the women only took the drug after the first trimester. This mistake diluted the results and produced a result that showed there was no increased risk.

[6] Jon T. Anderson, MD, PhD, *Ondansetron Use in Early Pregnancy and the Risk of Congenital Malformations – A Register Based Nationwide Cohort Study*. International Society of Pharmaco-epidemiology, Montreal, Canada; 2013. Abstract 25, Pregnancy session 1.

22. A Swedish study in 2014 used birth records from 1998 to 2012 and found that if women used Zofran during early pregnancy, their child was **62% more likely** to be born with a congenital malformation.[7]

23. Australian researchers used birth records to study all births in Western Australia from 2002 to 2005 and found that the risk of birth defects **increased by 20%** if the child was exposed to ondansetron in the first trimester.[8]

24. Researchers at Harvard University and Boston University concluded that pregnant women who had taken ondansetron during the first trimester of pregnancy were **2.37 times more likely** to deliver a baby with a birth defect.[9]

25. GSK's actual knowledge of the risk of birth defects goes as far back as the 1980's. GSK submitted data from four animal studies to the FDA with their new drug application packet and these studies clearly showed Zofran was harmful to fetuses.[10] The animal studies showed high concentrations of ondansetron's active ingredient did transfer through the placenta to the unborn fetus. The exposure to ondansetron caused these animals to suffer congenital defects, malformations, developmental retardation, incomplete bone growth, intrauterine deaths, etc. GSK concealed and misrepresented this material information.

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[7] Congenital malformation is a category that includes atrial septal defects, ventricular septal defects, and atrioventricular septal defects. Danielsson B, Wikner BN, Reprod Toxicology 2014 Dec; 50:134-7, *Use of Ondansetron During Pregnancy & Congenital Malformations in the Infant*.

[8] Out of 96,968 births, there were only 251 women prescribed ondansetron. Researchers attribute this small sample size to the fact that they only had access to medical records through Australia's Pharmaceutical Benefits Scheme (similar to Medicare) and the overwhelming majority of women who were prescribed ondansetron had private health insurance, but they did not have access to that data. Andrew W. Gill, *Off-Label Use of Ondansetron in Pregnancy in Western Australia*, BioMed Research International Volume 2013 (2013), Article ID 909860, 8 pages.

[9] Anderka M. Mitchell, *Medications Used to Treat Nausea and Vomiting of Pregnancy and the Risk of Selected Birth Defects*, 2012; 94(1):22-30. Epub. 2011 Nov 19.

[10] GSK submitted data from four animal studies with its new drug application ("NDA") for Zofran. New drug application for Zofran number: NDA 20-0007. Study 1: Study No. R10937 I.V. Segment II teratological study of rats; Study 2: Study No. R10873 I.V. Segment II teratological study of rabbits; Study 3: Study No. R10590 Oral Segment II teratological study of rats; Study 4: Study No. L10649 Oral Segment II teratological study of rabbits.

26. GSK's actual knowledge can also be traced back to 2006 to an independent study of fetal tissue samples from 41 pregnant patients who terminated their pregnancy. The researchers concluded, "A significant amount of ondansetron was present in all embryonic compartments. The developmental significance of this drug exposure requires further investigation, i.e. whole embryo culture."[11]

27. GSK gained actual knowledge in 1992 when reports from patients began to associate Zofran with birth defects. Between January 1, 1991 and April 30, 2015, 475 cases of birth defects caused by Zofran have been identified. About 170 of the 475 reports showed congenital heart defects.[12] Other reports included intrauterine death, stillbirth, kidney malformation, musculoskeletal anomalies, and orofacial anomalies. GSK concealed and misrepresented this material information.

28. To summarize, there is substantial evidence dating back to 1992 that Zofran presented an unreasonable risk of harm in pregnant women and caused birth defects. GSK had actual knowledge since the company applied for approval with the FDA that Zofran was unreasonably dangerous. First, GSK knew that Zofran crosses the placental barriers in humans and can cause harm to the baby. Second, GSK's four animal studies submitted with their new drug application showed Zofran significantly increases the risk of birth defects. Also, GSK admits on their warning label, that animal studies cannot be relied upon to determine if a drug is safe for pregnant women. Third, GSK received up to 175 reports of birth defects from patients who took Zofran over the years. Finally, the four newest studies indicate, undoubtedly, that

[11] Department of Obstetrics and Gynaecology, The Chinese University of Hong Kong, Prince of Wales Hospital, Shatin, Hong Kong, *Placental Transfer of Ondansetron During Early Human Pregnancy.* 2006.
[12] Monheit, Michael, *Zofran Linked to Birth Defects, Adverse Fetal Outcomes in Hundreds of Adverse Event Reports*, The Legal Examiner, July 2015.

Zofran greatly increases the risk of birth defects. The studies were well-controlled, reliable, and performed on a very large sample size over a long period of time.

29. In 2012, GSK pled guilty to criminal charges brought by the United States Department of Justice and paid a fine in the amount of $1,042,612,800.00 for:

> "[V]iolations of Title 21, United States Code, Sections 331(a), 333(a)(1) and 352, namely, the introduction into interstate commerce of the misbranded drugs...violation of Title 21, United States Code 331(e), 331(a)(1), and 355(k)(1), namely, that GSK failed to report data relating to clinical experience, along with other data and information...to the FDA in mandatory reports, all in violation of the Food, Drug and Cosmetic Act....**Zofran: During the period January 1, 2002 through December 31, 2004, GSK knowingly: (a) promoted the sale and use of Zofran for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including hyperemesis or pregnancy-related nausea), and some of which were not medically accepted indications...(b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Zofran concerning the uses described in section (a) of this sub-paragraph; and (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran, in violation of the Federal Anti-Kickback Statute...."**[13]

30. In the civil settlement agreement, GSK also admitted to: promoting the sale and use of Zofran for off label use of morning sickness; making false representations about Zofran's safety; and paying illegal kickbacks to healthcare providers to them to prescribe Zofran. The combined civil settlement and criminal fines total over $3 billion.

FACTS SPECIFIC TO PLAINTIFF

31. Plaintiff, LISA MARIE REED, is the mother and natural guardian of B.R.

32. Ms. REED was prescribed Zofran dissolvable tablets to treat morning sickness during her entire pregnancy with B.R.

33. Ms. REED took Zofran dissolvable tablets orally as directed throughout her entire pregnancy, beginning shortly after becoming pregnant in November 2006.

34. Ms. REED gave birth to her child, B.R., on July 10, 2007.

[13] This is an excerpt from the "Settlement Agreement" in the case United States v. GlaxoSmithKline (criminal docket number: 1:12cr10206RWZ) in the United States District Court in the District of Massachusetts.

35. Plaintiff's minor child, B.R., was born with congenital heart defects, specifically atrioventricular blocks in two chambers of his heart, caused by his exposure to ondansetron (Zofran) while *in utero.*

36. Ms. REED's physician would have never prescribed Zofran during the first trimester, or at all, had the unreasonable risk of birth defects been disclosed instead of concealed by GSK. Ms. REED and her physician would have used a safer alternative to treat morning sickness, or used no drugs at all to treat her morning sickness as the risks of Zofran greatly outweigh the benefits. Had Ms. REED not ingested Zofran during her pregnancy, the drug would have never been passed via the placenta to B.R. and the child would not have been born with congenital defects.

37. B.R. has no family history of any of the conditions from which the child suffers; and there is no genetic predisposition or genetic explanation for these conditions.

38. B.R. has a twin who was unaffected by Ms. REED's ingestion of Zofran during her pregnancy. When B.R. and his twin sibling began to walk and run, Ms. REED began to notice B.R.'s health issues. B.R. would become winded and exhausted much quicker than his twin while they were playing or doing other physical activities. It was at this time that it was discovered that B.R. suffered from congenital heart defects caused from his exposure to Zofran while Ms. REED was pregnant.

39. B.R. was diagnosed in October 2012 with high degree second degree atrioventricular block and a third degree atrioventricular block as a result of B.R.'s exposure to the drug ondansetron while in utero.

40. B.R. was admitted to Wolfson's Children's Hospital for observation after experiencing a syncopal event; it was determined the B.R. needed a pacing system.

41. On November 14, 2012, B.R. underwent surgery for implantation of the dual chamber epicardial pacing system.

42. B.R. suffered severe and permanent birth defects that he will suffer from for the rest of his life, as well as, physical and emotional pain, diminished enjoyment of life due to his physical limitations, lifelong medical treatment, surgeries, medical care, medication, and future loss of the ability to earn income.

STATEMENT OF JURISDICTION AND VENUE

43. This Court has diversity jurisdiction over these claims pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because GSK and Plaintiff, LISA MARIE REED are citizens of different states.

44. Venue is proper in this judicial district under 28 U.S.C § 1391 since a substantial part of the events giving rise to the claims alleged occurred in this district and certain parties are citizens of this district or regularly engage in business in this district.

45. GSK engaged in interstate commerce by fraudulently advertising, promoting, marketing, supplying, selling, and distributing pharmaceuticals (Zofran) to distributors, healthcare providers and retailers in every state in the United States. GSK has a registered agent located in this judicial district in Tallahassee, Florida, conducts substantial amounts of business in this jurisdiction from which they derive substantial revenue.

PARTIES

46. Plaintiff, LISA MARIE REED, is the mother and natural guardian of her child, B.R., who resides with Ms. REED. Plaintiff is a citizen of the United States and is domiciled in Jacksonville, Florida.

47. GlaxoSmithKline LLC is a limited liability company formed in the State of Delaware. GSK's sole member is GlaxoSmithKline Holdings, Inc., incorporated in Delaware, and has its principal place of business in Delaware. GSK has a registered agent in Florida, as required by Florida Statute, in Tallahassee, Florida.

COUNT I - NEGLIGENCE

48. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

49. GSK had a duty to Plaintiff to exercise reasonable care, and comply with existing standards of care of the pharmaceutical and healthcare industry in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, and/or distribution of Zofran into the stream of commerce, including a duty to warn consumers of potential dangerous side effects and a duty to ensure the product would not cause consumers to suffer unreasonable, dangerous side effects.

50. GSK failed to exercise reasonable care and failed to comply with existing standards of care in the pharmaceutical industry in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, labeling, testing, and distribution of Zofran into interstate commerce because GSK knew or should have known that using Zofran created an unreasonable risk of severe birth defects, and other serious side effects that have the potential to cause permanent injury or death.

51. GSK, and its agents / employees, failed to exercise reasonable care when they: failed to warn prescribing physicians of the dangerous propensity of this drug to cause serious birth defects when taken by pregnant mothers when this knowledge became available to GSK;

failed to properly label Zofran's packaging with the appropriate warnings regarding the risk to pregnant women; failed to add appropriate warning label to Zofran after GSK had knowledge of the propensity of this drug to cause birth defects; failed to perform any type of clinical or pre-clinical testing/research to determine if Zofran can be safely prescribed to pregnant women for treatment of nausea; heavily marketed Zofran and paid huge kickbacks to physicians to prescribe Zofran for morning sickness without testing to determine the risk of birth defects; sold Zofran without performing testing to determine the risk of birth defects; advertised Zofran for treatment of morning sickness without studying the risks of birth defects; purposely falsely represented that Zofran was safe for pregnant women when it was not; falsely represented the results of an animal study stating that the study showed no harm to fetuses, when the data actually showed toxicity, intrauterine death, developmental retardation, and incomplete bone growth in rats and rabbits; failed to advise Plaintiff, healthcare providers, the FDA, and the medical community of abundant evidence that Zofran caused birth defects when used by pregnant women for morning sickness.

52. GSK did not act with reasonable care when they purposely and systematically continued to manufacture, market, advertise, and distribute Zofran to Plaintiff and other consumers with actual knowledge that Zofran cause birth defects when taken by pregnant women.

53. GSK's negligent actions are the legal and proximate cause of Plaintiff's injuries, harm and future economic loss which Plaintiff will suffer for the remainder of his life.

54. But for GSK's negligent actions regarding the manufacturing, marketing, advertising, and distributing of Zofran, Ms. Reed would not have taken Zofran during her pregnancy and B.R. would not have suffered these permanent injuries as a result.

55. GSK knew or should have known that Plaintiff would foreseeably suffer injury as a direct result of GSK's failure to exercise reasonable care, as described above.

56. As a result of GSK's negligent actions, B.R. suffered severe and permanent birth defects that he will suffer from for the rest of his life, as well as, physical and emotional pain, diminished enjoyment of life, lifelong medical treatment, surgeries, medical care, medication, and future loss of the ability to earn income.

57. Due to GSK's negligent actions, Ms. Reed has also suffered and will continue to suffer severe emotional distress and mental anguish resulting from having a child with serious health issues.

58. Due to GSK's negligent actions, B.R. required and will continue to require extensive health-care and medical treatment for the rest of his life. Therefore, Plaintiff and her son have incurred and will incur substantial expense throughout the lifetime of B.R.

59. GSK's conduct was clearly willful, deliberate, and reckless, and a complete disregard for the well-being and safely of its consumers. For this, Plaintiff is justified in seeking a large award of punitive damages.

COUNT II – NEGLIGENCE PER SE

60. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

61. GSK had a duty to Plaintiff to exercise reasonable care, and comply with existing laws, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, and/or distribution of Zofran into the stream of commerce, including a duty to ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

62. GSK failed to exercise reasonable care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, labeling, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk or serious birth defects.

63. GSK, its agents, and/or employees failed to exercise reasonable care and violated the following statutes: 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b; and 21 C.F.R. §§ 201.57, 201.128.

64. GSK is negligent per se because the laws violated by GSK were designed to protect Plaintiff and similarly situated persons and to protect against the type of harm Plaintiff suffered here.

65. GSK knew or should have known that Zofran significantly increased the risk of birth defects, but continued to falsely market, manufacture, and distribute Zofran to the Plaintiff and other consumers.

66. It was foreseeable to GSK that Plaintiff would suffer injury as a result of GSK's failure to exercise reasonable care, as set forth above.

67. GSK's negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiff suffered and will continue to suffer for the rest of his life.

68. But for Plaintiff taking Zofran, her son would not have suffered those injuries and damages described herein.

69. As a result of the foregoing acts and omissions, B.R. was caused to suffer severe birth defects that are permanent in nature, physical pain and mental anguish, diminished enjoyment of life, and the need for lifelong medical care, monitoring, and/or medications.

70. Plaintiff, LISA REED, has suffered severe emotional distress and mental anguish as a result of her son's injuries caused by the negligent actions of GSK.

71. As a result of the foregoing acts, Plaintiff, B.R., requires and will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff, LISA REED, is informed and alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

72. For the reasons above, Plaintiff has been damaged by GSK's negligent conduct. It is also clear that GSK's conduct is willful, wanton, and reckless, and indicates a disregard for human life and, therefore, rises to the level of gross negligence. GSK's conduct justifies a large award of punitive damages.

COUNT III – STRICT PRODUCTS LIABILITY

(a.) Duty to Warn

73. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

74. GSK knew or should have known that Zofran could cause birth defects. GSK had a duty to warn prescribing physicians and all members of the medical community authorized to dispense and administer prescription drugs of the increased risk for birth defects caused by Zofran so the physicians could properly warn consumers, such as Plaintiff, of the risks associated with Zofran.

75. GSK failed to warn Plaintiff (through Plaintiff's prescribing physician) that Zofran was associated with and/or caused birth defects; and GSK has concealed and continues to conceal that Zofran is associated with or can cause birth defects.

76. Zofran was and is unreasonably defective and dangerous due to inadequate warnings, warning labels, and instructions.

77. GSK failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of a child developing birth defects from his/her mother ingesting Zofran while pregnant, from which Plaintiff suffered. This risk is not an open or obvious risk that is a matter of common knowledge and Plaintiff did not assume the risk of her son being born with birth defects. Not only did GSK fail to warn physicians and consumers of the risks of birth defects; but they aggressively marketed Zofran as a miracle treatment for morning sickness knowing its potential to cause birth defects.

78. Defendants are strictly liable to Plaintiff for injuries and damages resulting from GSK's failure to warn. GSK'S failure to warn was the direct and proximate cause of Plaintiff's injuries described above.

(b.) Defective Design

79. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

80. Zofran was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied, and/or placed into the stream of commerce by GSK and was defective at the time it left the control of GSK and reached the Plaintiff without change.

81. Zofran was not reasonably safe for this off-label use and was defective as a matter of law with respect to its design in that the risks of using Zofran exceeded its benefits and a safer alternative treatment was available.

82. Neither Plaintiff's prescribing physician, health-care providers, nor Plaintiff knew, or had any reason to know, at the time of their use of Zofran of the existence of the defects in the product described above.

83. Plaintiff, LISA REED, ingested Zofran throughout the first trimester of her pregnancy, for its prescribed purpose, to treat morning sickness, and in the manner prescribed.

84. Plaintiff, LISA REED, was not able to discover Zofran's defects and risks by any type of reasonable efforts.

85. As a direct and proximate result of the design defect of the drug Zofran, Plaintiff's son, B.R., suffered severe birth defects that are permanent in nature, physical and mental anguish, diminished enjoyment of life, and the need for lifelong medical treatment, monitoring and/or medications.

86. Plaintiff, LISA REED, has suffered severe emotional distress and mental anguish as a result of her son's injuries caused by the negligent actions of GSK.

87. As a result of the foregoing acts, Plaintiff, B.R., requires and will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff, LISA REED, is informed and alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

88. For the reasons above, Plaintiff has been damaged by GSK's negligent conduct. It is also clear that GSK's conduct is willful, wanton, and reckless, and indicates a disregard for human life and, therefore, rises to the level of gross negligence. GSK's conduct justifies an award of punitive damages.

(c.) Breach of Warranty of Fitness for Particular Purpose

89. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

90. GSK is a merchant with respect to goods of the kind Plaintiff received, namely prescription drugs. GSK warranted that Zofran was fit for the particular purpose of being used safely in the treatment of pregnancy-related morning sickness.

91. Plaintiff's physician and Plaintiff relied on GSK's skill and judgment when prescribing Zofran and deciding to use Zofran for the treatment of Plaintiff's morning sickness.

92. Zofran was not fit for the particular purpose for which GSK warranted it to be used because the product presents unreasonable risks of birth defects. It was defective in design and failed to provide adequate warnings and instructions, and was unreasonably dangerous. GSK's product was dangerous to an extent beyond the expectations of Plaintiff, or other consumers, with common knowledge of the product's characteristics.

93. GSK breached the implied warranty of fitness for a particular purpose because the product was not safe, not adequately packaged and labeled, did not conform to representations made by GSK.

COUNT IV – FRAUDULENT MISREPRESENTATION

94. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

95. GSK fraudulently misrepresented to the medical community and to Plaintiff the following material facts concerning the character or quality of Zofran: Zofran was safe for

treating pregnancy-related nausea; Zofran had undergone testing to support the assertion that it is safe for women to take while pregnant; Zofran did not pose any risks of birth defects when taken during pregnancy; and Zofran's designation of "Pregnancy Category B" ensured Zofran was safe to take while pregnant and did not pose a risk of birth defects; GSK had no knowledge that Zofran was not safe for pregnant women.

96. These facts were material.

97. GSK knew these material statements were false when the company made them; or GSK should have known they were false because it is clear that GSK had actual knowledge from many different sources albeit patient reports or test results, as alleged herein.

98. GSK made these misrepresentations with the intention to induce physicians to prescribe Zofran to pregnant women and to induce these women to believe Zofran was safe to take while pregnant. The intent to induce is evident by GSK's extensive marketing campaign in which the company heavily promoted, and paid kickbacks to doctors, to prescribe Zofran for this 'off-label' use of treating morning sickness. GSK exploited a need in the marketplace for this type of drug, cut corners in clinical trials to get Zofran to market faster and gain an unfair advantage over competitors then, worst of all, fraudulently represented to pregnant women that Zofran was safe, all for the sake of profit. At the heart of GSK's extensive marketing campaign and huge sales force was the intentional, material misrepresentation that Zofran was safe for pregnant women and posed no risk of birth defects. GSK intentionally defrauded and deceived the medical community and the general public, and showed an utter disregard for human life.

99. At the time these misrepresentations were made by GSK, Plaintiff used Zofran, and was unaware of the falsity of the representations and reasonably believed them to be true.

100. Plaintiff's prescriber did rely on these representations and was induced by them to prescribe Zofran to Plaintiff during her pregnancy to treat morning sickness. Plaintiff did rely on these representations as well and was induced to use Zofran to treat morning sickness during her pregnancy. Plaintiff would have never taken Zofran had she known the truth concerning the risks of birth defects to her child; she would have used an alternative treatment method, or used nothing.

101. As a result of the foregoing fraudulent misrepresentations, B.R. was caused to suffer severe birth defects that are permanent in nature, physical pain and mental anguish, diminished enjoyment of life, and the need for lifelong medical care, monitoring, and/or medications.

102. Plaintiff, LISA REED, has suffered severe emotional distress and mental anguish and anxiety as a result of having a child with health issues, caused by the fraudulent actions of GSK.

103. As a result of the these fraudulent acts, Plaintiff, B.R., requires and will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff, LISA REED, is informed and alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

104. For the reasons above, Plaintiff has been damaged by GSK's fraudulent conduct. It is also clear that GSK's conduct is willful, wanton, and reckless, and indicates a disregard for human life and, therefore, rises to the level of gross negligence. GSK's conduct justifies an award of punitive damages.

COUNT V – FRAUDULENT CONCEALMENT

105. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

106. GSK purposely concealed or failed to disclose to Plaintiff or Plaintiff's healthcare providers the following material facts: GSK was illegally paying and offering to pay doctors remuneration to promote and prescribe Zofran; Zofran had not (and still has not) been tested or studied in pregnant women at all; *in utero* exposure to Zofran does increase the risk of birth defects; the risks of birth defects associated with the consumption of Zofran by pregnant women were not adequately tested prior to GSK's marketing of Zofran; the safety of Zofran for treating morning sickness has not been established; Zofran is not safe for treating morning sickness; and GSK's internal data and information showed a causal link between Zofran use in pregnant women and birth defects.

107. GSK knew or should have known that these material facts should be disclosed to Plaintiff and Plaintiff's health care providers as GSK had a duty, as a prescription drug manufacturer, to inform Plaintiff of the risks of birth defects when using Zofran during pregnancy.

108. GSK knew or should have known that physicians, hospitals, healthcare providers, and pregnant women, such as Plaintiff, had no way to determine the truth behind GSK's concealment of these material facts.

109. GSK knew their concealment of these facts would induce Plaintiff, her healthcare providers, other consumers, hospitals, physicians to prescribe and use Zofran for the treatment of morning sickness.

110. Plaintiff and her healthcare providers did detrimentally rely on GSK's purposeful and fraudulent statements omitting material facts concerning the safety of using Zofran to treat morning sickness in pregnant women.

111. As a result of the foregoing fraudulent misrepresentations, B.R. was caused to suffer severe birth defects that are permanent in nature, physical pain and mental anguish, diminished enjoyment of life, and the need for lifelong medical care, monitoring, and/or medications.

112. Plaintiff, LISA REED, has suffered severe emotional distress and mental anguish as a result of her son's injuries caused by the fraudulent actions of GSK.

113. As a result of the these fraudulent acts, Plaintiff, B.R., requires and will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff, LISA REED, is informed and alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

114. For the reasons above, Plaintiff has been damaged by GSK's fraudulent conduct. It is also clear that GSK's conduct is willful, wanton, and reckless, and indicates a disregard for human life and, therefore, rises to the level of gross negligence. GSK's conduct justifies an award of punitive damages.

COUNT VI – NEGLIGENT MISREPRESENTATION

115. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

116. GSK negligently misrepresented to the medical community and to Plaintiff the following material facts concerning the character or quality of Zofran: Zofran was safe for

treating pregnancy-related nausea; Zofran had undergone testing to support the assertion that it is safe for women to take while pregnant; Zofran did not pose any risks of birth defects when taken during pregnancy; and Zofran's designation of "Pregnancy Category B" ensured Zofran was safe to take while pregnant and did not pose a risk of birth defects.

117. These representations made by GSK were false and misleading and were made without regard to their truth or falsity.

118. Plaintiff's prescriber did rely on these representations and was induced by them to prescribe Zofran to Plaintiff during her pregnancy to treat morning sickness. Plaintiff did personally rely on these representations as well and was induced to use Zofran to treat morning sickness during her pregnancy. Plaintiff was justified in relying on these representations because it is common practice for a Physician or patient to rely on representations made by the manufacturer of a drug via a warning label or instructions with regards to the safety and risks of a particular drug.

119. As a result of the foregoing negligent misrepresentations, B.R. was caused to suffer severe birth defects that are permanent in nature, physical pain and mental anguish, diminished enjoyment of life, and the need for lifelong medical care, monitoring, and/or medications.

120. Plaintiff, LISA REED, has suffered severe emotional distress and mental anguish as a result of her son's injuries caused by the negligent misrepresentations of GSK.

121. As a result of the these negligent misrepresentations, Plaintiff, B.R., requires and will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff, LISA REED, is informed and alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

122. For the reasons above, Plaintiff has been damaged by GSK's negligent conduct. It is also clear that GSK's conduct is willful, wanton, and reckless, and indicates a disregard for human life and, therefore, rises to the level of gross negligence. GSK's conduct justifies an award of punitive damages.

COUNT VII – BREACH OF EXPRESS WARRANTY

123. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

124. GSK expressly warranted the following: Zofran was safe for treating pregnancy-related nausea; proper testing and research to determine side effects of Zofran use in pregnant women had been completed; Zofran's use during pregnancy did not increase the risk of birth defects; and Zofran's designation as a "Pregnancy Category B" drug expressed it was safe for use by pregnant women for morning sickness.

125. Zofran does not conform to these express representations because Zofran is not safe and presents unreasonable risk of serious side effects, including birth defects and intrauterine death, which GSK did not warn about. As a direct and proximate result of the breach of these express warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm, mental anguish and economic loss.

126. Plaintiff, LISA REED, and her healthcare providers did rely on these express warranties.

127. Physicians, and others in the medical community, who are authorized to prescribe medicine relied on these express warranties when forming their professional opinion to recommend, dispense, or prescribe Zofran for the treatment of morning sickness.

128. GSK knew or should have known that these express representations were false and misleading, as demonstrated by Plaintiff's injuries, as well as many other consumers who used Zofran for this purpose warranted by GSK.

129. As a result of the foregoing breaches of expressed warranties, B.R. was caused to suffer severe birth defects that are permanent in nature, physical pain and mental anguish, diminished enjoyment of life, and the need for lifelong medical care, monitoring, and/or medications.

130. Plaintiff, LISA REED, has suffered severe emotional distress and mental anguish as a result of her son's injuries caused by the breached warranties of GSK.

131. As a result of the these breached express warranties, Plaintiff, B.R., requires and will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff, LISA REED, is informed and alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

132. For the reasons above, Plaintiff has been damaged by GSK's conduct. It is also clear that GSK's conduct is willful, wanton, and reckless, and indicates a disregard for human life and, therefore, rises to the level of gross negligence. GSK's conduct justifies an award of punitive damages.

COUNT VIII – FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES § 501.204(1)

133. Plaintiff repeats, reiterates and re-alleges each allegation of this Complaint contained in each of the foregoing numbered paragraphs inclusive, with the same force and effect as if more fully set forth herein.

134. GSK engaged in a substantial amount of trade and commerce in the State of Florida.

135. GSK engaged unconscionable acts and unfair and deceptive business practices in the course of trade and commerce in Florida, as prohibited by Florida Statutes § 501.204(1), with regards to the purposeful, fraudulent misrepresentations and concealment of material facts as described in this Complaint.

136. Plaintiff suffered injury as a direct and proximate result of these unconscionable, unfair and deceptive business practices. Plaintiff has lifelong injuries due to the deceptive, unethical, and unconscionable misrepresentations and concealments of material facts that were known to GSK. Had the risks of using Zofran while pregnant been disclosed to the general public, as required by law, many consumers would not have been harmed.

137. GSK is liable to Plaintiff for all statutory, consequential damages, and fees and costs, resulting from the violation of § 501.204.

COUNT IX – LOSS OF CONSORTIUM

138. Plaintiff's repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

139. B.R. is a minor child who is dependent upon his mother, Plaintiff LISA REED, for support.

140. As a direct and proximate result of the Defendant's negligence, misrepresentations, and fraud, MS. REED has been deprived of the society, love, affection, companionship, care and services of her child, B.R., and is entitled to recovery for the loss.

141. Plaintiff seeks all damages available against Defendant as a result of the loss of consortium of her child.

DEMAND FOR JURY TRIAL

Plaintiff exercises her right to demand a jury trial pursuant to Rule 36 of the Federal Rules of Civil Procedure and as declared by the Seventh Amendment to the United States Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against GSK on each of the above causes of action and as follows:

1) for general damages in excess of the jurisdictional minimum of this Court;
2) for medical, incidental and hospital expenses as the evidence will prove;
3) for pre-judgment and post-judgment interest as provided by law
4) for consequential damages in excess of the jurisdictional minimum of this Court;
5) for compensatory damages in excess of the jurisdictional minimum of this Court;
6) for punitive damages in excess of the jurisdictional minimum of this Court;
7) for punitive damages in an amount in excess of any jurisdictional minimum of the Court in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;
8) for attorneys' fees, expenses and costs to bring this action; and
9) for such further relief and other relief as this Court deems necessary, just, and proper.

LAW OFFICES OF
MUENCH AND LUCA, PLLC

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Jacksonville, FL 32202
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Attorney for Plaintiff

3:15-cv-1463-J-20PDB

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
REED, LISA M., individually and as natural guardian of B.R., her minor child

(b) County of Residence of First Listed Plaintiff Duval County, Florida
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Law Offices of Muench & Luca, PLLC
Jonathan J. Luca, Esquire
438 East Monroe Street, Jacksonville, FL 32202, Tel: 904-358-8778

DEFENDANTS
GLAXOSMITHKLINE, LLC

County of Residence of First Listed Defendant Philadelphia, PA
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
Brief description of cause:
PRESCRIPTION DRUG PRODUCT LIABILITY, NEGLIGENCE, FRAUD

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE Dennis F. Saylor (Dist. Massachusetts) DOCKET NUMBER Multidist Lit Case No -- 2657

DATE 12/08/2015

SIGNATURE OF ATTORNEY OF RECORD 0625523 FL.

FOR OFFICE USE ONLY

RECEIPT# JAX 018524 AMOUNT 400.00 APPLYING IFP — JUDGE 20 MAG. JUDGE PDB