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SUPERIOR COURT FOR THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

SONYA LAMPKIN, Individually and as Parent and Natural Guardian of J.S., a Minor ,

Plaintiffs,

v.

GLAXOSMITHKLINE LLC d/b/a GLAXOSMITHKLINE; MCKESSON CORPORATION, and DOES 1 through 50, inclusive,

Defendants.

CASE NO. RG15761042

COMPLAINT FOR DAMAGES

1. **Negligence;**
2. **Negligence Per Se;**
3. **Strict Products Liability;**
4. **Fraudulent Misrepresentation;**
5. **Fraudulent Concealment;**
6. **Negligent Misrepresentation;**
7. **Breach of Express Warranty; and**
8. **Breach of Implied Warranty of Merchantability and Fitness for Particular Use.**

DEMAND FOR JURY TRIAL

COMES NOW Plaintiff, Sonya Lampkin, individually and on behalf of her son, J.S., a minor, ("Plaintiff"), who by and through the undersigned counsel hereby submit this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "Defendant") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to J.S. as a result of his prenatal exposures to the prescription drug Zofran®, also known as ondansetron. In support of this Complaint, Plaintiff

alleges the following.

INTRODUCTION

1. Zofran is a powerful drug developed by GSK to treat only those patients who were afflicted with the most severe nausea imaginable – that suffered by cancer patients undergoing chemotherapy or radiation treatments.

2. The U.S. Food and Drug Administration ("FDA") approved Zofran in 1991 for use in cancer patients who required chemotherapy or radiation therapy.

3. Although the only FDA approval for this drug was for seriously ill patients, GSK marketed Zofran "off label" as a safe and effective treatment for the very common side effect of a normal pregnancy - pregnancy-related nausea and vomiting - otherwise known as "morning sickness." GSK did this despite having knowledge that such representations were utterly false, as GSK had never once undertaken a single study on the effects of this powerful drug on a pregnant mother or her growing child *in utero*. Unlike another anti-nausea prescription drug available on the market – which is FDA-approved in the United States for treating morning sickness in pregnant women – GSK never conducted a single clinical trial before marketing Zofran to pregnant women. GSK simply chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment during pregnancy. GSK knowingly avoided conducting these studies because they would have hampered its marketing of Zofran and decreased profits by linking the drug to serious birth defects. GSK's conduct was tantamount to using expectant mothers and their unborn children as human guinea pigs.

4. As a result of GSK's fraudulent marketing campaign, Zofran was placed into the hands of unsuspecting pregnant women throughout the United States. These women ingested the drug because they innocently believed that Zofran was an appropriate drug to treat symptoms of morning sickness. When they ingested the drug, these pregnant women had no way of knowing that Zofran had never been studied in pregnant women, much less shown to be a safe and effective treatment for pregnancy-related nausea.

5. By contrast, GSK knew that Zofran was unsafe for ingestion by expectant mothers. In the 1980s, GSK conducted animal studies which revealed evidence of toxicity, intrauterine

deaths, and malformations in offspring. These studies also showed that Zofran's active ingredient was being transferred through the placental barrier of pregnant mammals to fetuses. A later study conducted in humans confirmed that ingested Zofran readily crossed the human placenta barrier and exposed fetuses to substantial concentrations. GSK did not disclose this information to pregnant women or their physicians.

6. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date. GSK never disclosed these reports to pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological studies that have demonstrated an elevated risk of developing birth defects such as those suffered in this case. GSK has not disclosed this to pregnant women or their physicians. Instead, GSK sales representatives specifically marketed and promoted Zofran as a morning sickness drug throughout the relevant time periods discussed herein.

7. In 2012, GSK pled guilty to criminal charges lodged by the United States of America, through the Department of Justice, for its "off-label" promotion of its drugs for uses never approved by the FDA.

8. At or around the same time, GSK also entered civil settlements with United States that included more than $1 billion in payments to the federal government for its illegal marketing of various drugs, including Zofran.

9. GSK's written agreement with the United States reports that GSK settled claims that GSK:

(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 and pregnancy-related nausea)"

(b) "made and/or disseminated unsubstantiated and false representations about the safety and efficacy of Zofran concerning the uses described in subsection (a) [hyperemesis and pregnancy-related nausea]"

(c) "offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran"

(Settlement Agreement, p. 5, July 2, 2012.)

10. GSK's conduct has caused devastating, irreversible, and life-long consequences and suffering to innocent newborns and their families, like Plaintiff herein.

11. Plaintiff's minor child, J.S., was born in 2010 with a congenital heart defect after his mother, Plaintiff Sonya Lampkin, was prescribed and began taking Zofran beginning early in her first trimester of pregnancy to alleviate the symptoms of morning sickness. After birth, it was discovered that J.S. suffered from a serious heart defect known as supraventricular tachycardia.

12. Had Plaintiff known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, she never would have taken Zofran, and her child never would have been injured as described herein.

13. Plaintiff brings claims for compensatory and punitive damages, as well as equitable relief in an effort to ensure that similarly situated mothers-to-be are fully informed about the risks, benefits and alternatives attending drugs marketed for use in pregnant women, and such other relief deemed just and proper arising from injuries and birth defects as a result of exposure to Zofran.

VENUE

14. Venue is proper in this Court because plaintiff resides in the County of Alameda, California and a substantial part of the events, omissions, and acts giving rise to the plaintiff's injuries occurred in this county.

15. Venue is also proper in this Court because defendant advertised, promoted, supplied, and sold pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public throughout Alameda County and the State of California.

PARTIES

16. Plaintiff, Sonya Lampkin, the mother and natural guardian of J.S., who lives with Ms. Lampkin. Plaintiff is domiciled in Oakland, Alameda County, California.

17. GSK is a limited liability company organized under the laws of the State of Delaware. GSK's sole member is GlaxoSmithKline Holdings, Inc., which is a Delaware corporation, and which has identified its principal place of business in Wilmington, Delaware.

18. GSK is the successor in interest to Glaxo, Inc. and Glaxo Welcome Inc. Glaxo, Inc. was the sponsor of the original New Drug Application ("NDA") for Zofran. Glaxo, Inc., through its division Cerenex Pharmaceuticals, authored the original package insert and labeling for Zofran, including warnings and precautions attendant to its use. Glaxo Wellcome Inc. sponsored additional NDAs for Zofran, monitored and evaluated post-market adverse event reports arising from Zofran, and authored product labeling for Zofran. The term GSK used herein refers to GSK, its predecessors Glaxo, Inc. and Glaxo Wellcome Inc., and other GSK predecessors and/or affiliates that discovery reveals were involved in the testing, development, manufacture, marketing, sale and/or distribution of Zofran.

19. At all relevant times, GSK conducted business in the State of California and have derived substantial revenue from products, including Zofran, sold in this State.

20. Defendant McKesson Corporation is a Delaware corporation with its a principal place of business in San Francisco, California. Plaintiff is informed and believes that McKesson was involved in the manufacture, distribution, marketing, sale, labeling, and design of Zofran as detailed below. Specifically, McKesson is the 16th largest industrial corporation in America, with over $800 billion in revenue every year. McKesson's own website states that "McKesson is everywhere" in healthcare. McKesson is the sole supplier of numerous pharmaceuticals to many of the largest pharmacies and drug suppliers in the nation including pharmacies such as Wal-Mart, Safeway, Valu-Rite, and numerous others. Upon information and belief, McKesson marketed sold and distributed the Zofran ingested by plaintiff by distributing Zofran to the pharmacy or drug store where plaintiff purchased Zofran. At all times herein mentioned, McKesson was the actor engaged in the acts herein alleged, acting through its agents and employees, and at all times, the actions and omissions asserted in this pleading were committed by agents or employees acting with the purpose and scope of said agency and employment.

PERTINENT BACKGROUND ON ZOFRAN

21. Zofran is a prescription drug indicated for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting and post-operative nausea and/or vomiting:

> **INDICATIONS AND USAGE**
> 1. Prevention of nausea and vomiting associated with highly emetogenic **cancer chemotherapy**, including cisplatin ≥ 50 mg/m2.
> 2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic **cancer chemotherapy**.
> 3. Prevention of nausea and vomiting associated with **radiotherapy** in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
> 4. Prevention of **postoperative nausea and/or vomiting**.

(GSK, Zofran Prescribing Information, Sept. 2014) (emphasis added.)

22. The medical term for nausea and vomiting is emesis, and drugs that prevent or treat nausea and vomiting are called anti-emetics.

23. Zofran is part of a class of anti-emetics called selective serotonin 5HT3 receptor antagonists. The active ingredient in Zofran is ondansetron hydrochloride, which is a potent and selective antagonist at the 5-hydroxytryptamine receptor type 3 (5-HT3).

24. Although 5-hydroxytryptamine (5HT) occurs in most tissues of the human body, Zofran is believed to block the effect of serotonin at the 5HT3 receptors located along vagal afferents in the gastrointestinal tract and at the receptors located in the area postrema of the central nervous system (the structure in the brain that controls vomiting). Put differently, Zofran antagonizes, or inhibits, the body's serotonin activity, which triggers nausea and vomiting.

25. Zofran was the first 5HT3 receptor antagonist approved for marketing in the United States. Other drugs in the class of 5HT3 receptor antagonist include Kytril® (granisetron) (FDA-approved 1994), Anzemet® (dolasetron) (FDA-approved 1997), and Aloxi® (palonosetron) (FDA-approved 2003).

26. Zofran is available as an injection (2 mg/mL), a premixed injection (32 mg/50ml and 4 mg/50 ml), oral tablets (4 mg, 8 mg and 24 mg); orally disintegrating tablets (4 mg and 8 mg) and an oral solution (4 mg/5 mL).

27. More specifically, GSK has obtained FDA approval for the following formations of Zofran:

a. NDA 20-007 – Zofran Injection (FDA approved January 4, 1991)

b. NDA 20-103 – Zofran Tablets (FDA approved December 31, 1992)

c. NDA 20-403 – Zofran Premixed Injection (FDA approved January 31, 1995)

d. NDA 20-605 – Zofran Oral Solution (FDA approved January 24, 1997)

e. NDA 20-781 – Zofran (a/k/a Zofran-Zydis) Orally Disintegrating Tablets (FDA approved January 27, 1999)

28. The FDA has never approved Zofran for the treatment of morning sickness or any other condition in pregnant women.

29. For GSK to market Zofran lawfully for the treatment of morning sickness in pregnant women, it must first adequately test the drug (including performing appropriate clinical studies) and formally submit to the FDA evidence demonstrating that the drug is safe and effective for treatment of morning sickness.

30. A team of the FDA's physicians, statisticians, chemists, pharmacologists, microbiologists and other scientists would then have an opportunity to: (a) review the company's data and evidence supporting its request for approval to market the drug; and (b) determine whether to approve the company's request to market the drug in the manner requested. Without first obtaining approval to market a drug for the treatment of pregnant women, a pharmaceutical company may not legally market its drug for that purpose.

31. GSK has not performed any clinical studies of Zofran use in pregnant women. GSK, however, had the resources and know-how to perform such studies, and such studies were performed to support another prescription drug that, unlike Zofran, is FDA-approved for the treatment of morning sickness.

32. GSK also has not submitted to the FDA any data demonstrating the safety or efficacy of Zofran for treating morning sickness in pregnant women. Instead, GSK has illegally circumvented the FDA-approval process by marketing Zofran for the treatment of morning sickness in pregnant women without applying for the FDA's approval to market Zofran to treat

that condition or any other condition in pregnant women. This practice is known as "off-label" promotion, and in this case it constitutes fraudulent marketing.

33. At all relevant times, GSK was in the business of and did design, research, manufacture, test, package, label, advertise, promote, market, sell and distribute Zofran, and GSK continues to market and sell Zofran today.

GSK's Knowledge That Zofran Presents an Unreasonable Risk of Harm to Fetuses Who Are Exposed to It During Pregnancy

Preclinical Studies

34. Since at least the 1980s, when GSK received the results of the preclinical studies that it submitted in support of Zofran's NDA 20-007, GSK has known of the risk that Zofran ingested during pregnancy in mammals crosses the placental barrier to expose the fetus to the drug. For example, at least as early as the mid-1980s, GSK performed placental-transfer studies of Zofran in rats and rabbits, and reported that the rat and rabbit fetuses were exposed prenatally to Zofran during pregnancy.

35. The placental transfer of Zofran during human pregnancy at concentrations high enough to cause congenital malformations has been independently confirmed and detected in every sample of fetal tissue taken in a published study involving 41 pregnant patients. The average fetal tissue concentration of Zofran's active ingredient was 41% of the corresponding concentration in the mother's plasma.

36. GSK reported four animal studies in support of its application for approval of NDA 20-0007: (1) Study No. R10937 I.V. Segment II teratological study of rats; (2) Study No. R10873 I.V. Segment II teratological study of rabbits; (3) Study No. R10590 Oral Segment II teratological study of rats; (4) Study No. L10649 Oral Segment II teratological study of rabbits. Although these preclinical teratogenicity studies in rats and rabbits were stated by the sponsor, GSK, to show no harm to the fetus, the actual data from the study showed something different. Specifically, the data revealed clinical signs of toxicity, premature births, intrauterine fetal deaths, and impairment of ossification (incomplete bone growth).

37. Study No. R10937 was a Segment II teratological study of pregnant rats exposed to Zofran injection solution. Four groups of 40 pregnant rats (160 total) were reportedly administered Zofran through intravenous (I.V.) administration at doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. Clinical signs of toxicity that were observed in the pregnant rats included "low posture, ataxia, subdued behavior and rearing, as well as nodding and bulging eyes." No observations were reported as teratogenic effects.

38. Study No. R10873 was a Segment II teratological study of pregnant rabbits exposed to Zofran injection solution. Four groups of 15 pregnant rabbits (60 total) were reportedly given Zofran doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. In this study, there was a reported increase in the number of intra-uterine deaths in the 4 mg/kg group versus lower-dose groups. The study also reported maternal weight loss in the exposed groups. Developmental retardation in off-spring and fetuses were noted – namely, areas of the parietal (body cavity) were not fully ossified, and the hyoid (neck) failed to ossify completely.

39. Study No. R10590 Oral Segment II teratological study of rats. Four groups of 30 pregnant rats (120 total) were given Zofran orally at doses of 0, 1, 4 and 15 mg/kg/day, respectively. Subdued behavior, labored breathing, which is a symptom of congenital heart defects, and dilated pupils were observed in the 15 mg/kg/day group. Body weight, gestational duration and fetal examinations were reported as normal, but "slight retardation in skeletal ossification" was noted in the offspring.

40. Study No. L10649 Oral Segment II teratological study of rabbits. Four groups of 14-18 pregnant rabbits (56-64 total) were given Zofran orally at doses of 0, 1, 5.5 and 30 mg/kg/day. The study reported lower maternal weight gain in all of the exposed groups, as well as premature delivery and "total litter loss," referring to fetal deaths during pregnancy in the 5.5 mg/kg/day group. Examination of the fetuses showed "slight developmental retardation as evident by incomplete ossification or asymmetry of skeleton."

41. Even if animal studies do not reveal evidence of harm to a prenatally exposed fetus, that result is not necessarily predictive of human response. For example, a drug formerly prescribed to alleviate morning sickness, thalidomide, is an infamous teratogenic in humans, but

animal studies involving the drug failed to demonstrate such an increased risk of birth defects in animals. GSK conducted studies of thalidomide and its toxicity before GSK developed Zofran and before it marketed Zofran for the treatment of morning sickness in pregnant women. Moreover, since at least 1993, GSK has stated in its prescribing information for Zofran that "animal reproduction studies are not always predictive of human response." Therefore, GSK has been aware since at least when it began marketing and selling Zofran that GSK could not responsibly rely on its animal studies as a basis for promoting Zofran use in pregnant women. But that is what GSK did.

Early Reports to GSK of Zofran-Related Birth Defects to GSK

42. At least as early as 1992, GSK began receiving reports of birth defects associated with the use of Zofran by pregnant women.

43. By 2000, GSK had received at least 32 reports of birth defects arising from Zofran treatment in pregnant women. These reports included congenital heart disease, dysmorphism, intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomaly, congenital musculoskeletal anomalies, and orofacial anomalies, among others.

44. In many instances, GSK received multiple reports in the same month, the same week and even the same day. For example, on or about September 13, 2000, GSK received three separate reports involving Zofran use and adverse events. For two of those incidents, the impact on the baby was so severe that the baby died.

45. From 1992 to the present, GSK has received more than **200** reports of birth defects in children who were exposed to Zofran during pregnancy.

46. The most commonly reported birth defects arising from Zofran use during pregnancy and reported to GSK were congenital heart defects, though multiple other defects such as orofacial defects, intrauterine death, stillbirth and severe malformations in newborns were frequently reported.

47. The number of events actually reported to GSK was only a small fraction of the actual incidents.

Epidemiology Studies Examining the Risk of Congenital Heart Defects in Babies Who Were Exposed to Zofran During Pregnancy

48. Epidemiology is a branch of medicine focused on studying the causes, distribution, and control of diseases in human populations.

49. Three recent epidemiological studies have examined the association between prenatal exposure to Zofran and the risk of congenital heart defects in babies. These studies include: (1) Pasternak, et al., *Ondansetron in Pregnancy and Risk of Adverse Fetal Outcomes*, New England Journal of Medicine (Feb. 28, 2013) (the "Pasternak Study"); (2) Andersen, et al., *Ondansetron Use in Early Pregnancy and the Risk of Congenital Malformations— A Register Based Nationwide Control Study*, presented as International Society of Pharmaco-epidemiology, Montreal, Canada (2013) (the "Andersen Study"); and (3) Danielsson, et al., *Ondansetron During Pregnancy and Congenital Malformations in the Infant* (Oct. 31, 2014) (the "Danielsson Study").

50. Each of these studies includes methodological characteristics tending to bias its results toward under-reporting the true risk of having a child with a birth defect. Notwithstanding these characteristics biasing the results toward the null hypothesis, all three studies show elevated risk ratios for cardiac malformations, including risk ratios greater than 2.0. In other words, the studies report that a mother exposed to Zofran had more than a doubled risk of having a baby with a congenital heart defect as compared to a mother who did not ingest Zofran during pregnancy.

51. The Pasternak Study included data from the Danish National Birth Registry and examined the use of Zofran during pregnancy and risk of adverse fetal outcomes. Adverse fetal outcomes were defined as: spontaneous abortion, stillbirth, any major birth defect, pre-term delivery, low birth weight, and small size for gestational age. There were 608,385 pregnancies between January 2004 and March 31, 2011 examined. The unexposed group was defined as women who did not fill a prescription for ondansetron during the exposure time window. The exposure time window was defined as the first 12 week gestational period. Notably, the median fetal age at first exposure to Zofran was ten weeks, meaning that half of the cases were first exposed to Zofran after organogenesis (organ formation). This characteristic of the study led to

an under-reporting of the actual risk of prenatal Zofran exposure. The study's supplemental materials indicated that women taking Zofran during the first trimester, compared to women who did not take Zofran, were 22% more likely to have offspring with a septal defect, 41% more likely to have offspring with a ventricular septal defect and greater than four-times more likely to have offspring with atrioventricular septal defect.

52. The Andersen Study was also based on data collected from the Danish Medical Birth Registry and the National Hospital Register, the same data examined in the Pasternak Study. The Andersen study examined the relationship between Zofran use during the first trimester and subgroups of congenital malformations. Data from all women giving birth in Denmark between 1997 and 2010 were included in the study. A total of 903,207 births were identified in the study period with 1,368 women filling prescriptions for Zofran during the first trimester. The Andersen Study therefore used a larger data set (13 years) compared to the Pasternak Study (seven years). Exposure to the drug was also defined as filling a prescription during the first trimester, and prescription data were obtained from the National Prescription Registry. The Andersen study reported that mothers who ingested Zofran during their first-trimester of pregnancy were more likely than mothers who did not to have a child with a congenital heart defect, and had a two- to four-fold greater risk of having a baby with a septal cardiac defect.

53. The Danielsson Study investigated risks associated with Zofran use during pregnancy and risk of cardiac congenital malformations from data available through the Swedish Medical Birth Registry. The Swedish Medical Birth Registry was combined with the Swedish Register of Prescribed Drugs to identify 1,349 infants born to women who had taken Zofran in early pregnancy from 1998-2012. The total number of births in the study was 1,501,434 infants, and 43,658 had malformations classified as major (2.9%). Among the major malformations, 14,872 had cardiovascular defects (34%) and 10,491 had a cardiac septum defect (24%). The Danielsson study reported a statistically significantly elevated risk for cardiovascular defects for mothers taking Zofran versus those who did not. The results reported that the mothers who took Zofran during early pregnancy had a 62% increased risk of having a baby with a cardiovascular

defect. Further, mothers who took Zofran during pregnancy had a greater than two-fold increased risk of having a baby with a septal cardiac defect, compared to mothers who did not take Zofran during pregnancy.

54. In summary, since at least 1992, GSK has had mounting evidence showing that Zofran presents an unreasonable risk of harm to babies who are exposed to the drug during pregnancy. GSK has been aware that Zofran readily crosses human placental barriers during pregnancy. GSK has also been aware that the animal studies of Zofran cannot reliably support an assertion that Zofran can be used safely or effectively in pregnant women. Since 1992, GSK has received hundreds of reports of major birth defects associated with prenatal Zofran exposure. GSK also has had actual and/or constructive knowledge of the epidemiological studies reporting that prenatal Zofran exposure can more than double the risk of developing congenital heart defects. As alleged below, GSK not only concealed this knowledge from healthcare providers and consumers in the United States, and failed to warn of the risk of birth defects, but GSK also illegally and fraudulently promoted Zofran to physicians and patients specifically for the treatment of morning sickness in pregnancy women.

GSK's Failure to Warn of the Risk of Birth Defects Associated with Prenatal Exposure to Zofran

55. Under federal law governing GSK's drug labeling for Zofran, GSK was required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." 21 C.F.R. § 201.57(e) (emphasis added).

56. GSK was also required to list adverse reactions that occurred with other drugs in the same class as Zofran. *Id.* § 201.57(g).

57. In the context of prescription drug labeling, "an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." *Id.*

58. Federal law also required GSK to revise Zofran's labeling "**to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.**" *Id.* § 201.57(e) (emphasis added).

59. GSK has received hundreds of reports of birth defects associated with the non-FDA-approved use of Zofran in pregnant women. GSK has failed, however, to disclose these severe adverse events to healthcare providers or expectant mothers, including Ms. LeClair and her prescribing healthcare provider.

60. Under 21 C.F.R. § 314.70(c)(2)(i), pharmaceutical companies were (and are) free to add or strengthen – without prior approval from the FDA – a contraindication, warning, precaution, or adverse reaction.

61. GSK thus had the ability and obligation to add warnings, precautions and adverse reactions to the product labeling for Zofran without prior approval from the FDA. GSK failed to do so.

62. Under 21 C.F.R. § 201.128, "if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put."

63. At least as of 1998, GSK knew well from its off-label promotion and payments to doctors, and its conspicuous increase in revenue from Zofran, and its market analyses of prescription data, that physicians were prescribing Zofran off-label to treat morning sickness in pregnant women and that such usage was associated with a clinically significant risk or hazard – birth defects.

64. GSK had the ability and obligation to state prominently in the Indications and Usage section of its drug label that there is a lack of evidence that Zofran is safe for the treatment of morning sickness in pregnant women. GSK failed to do so, despite GSK's knowledge that (a) the safety of Zofran for use in human pregnancy has not been established, and (b) there have been hundreds of reports of birth defects associated with Zofran use during pregnancy, and (c) epidemiology studies report an increased risk of birth defects in babies exposed to Zofran during pregnancy.

65. From 1993 to the present, despite mounting evidence of the birth defect risk, GSK's prescribing information for Zofran has included the same statement concerning use of Zofran during pregnancy:

> "**Pregnancy: Teratogenic Effects**: Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at I.V. doses up to 4 mg/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."

66. By contrast, the Product Monograph for Zofran in Canada states "**the safety of ondansetron for use in human pregnancy has not been established**," and that "**the use of ondansetron in pregnancy is <u>not</u> recommended**."

67. In the United States and in this State specifically, GSK has at all relevant times failed to include any warning disclosing any risks of birth defects arising from Zofran use during pregnancy in Zofran's prescribing information or other product labeling.

68. GSK's inclusion of the phrase "Pregnancy Category B" in Zofran's prescribing information refers the FDA's pregnancy categorization scheme applicable to prescription drugs in the United States. The FDA has established five categories to indicate the potential of a drug to cause birth defects if used during pregnancy. The current system of pregnancy labeling consists of five letter-categories (A, B, C, D, and X, in order of increasing risk).

69. GSK had the ability, and indeed was required, to update Zofran's label to reflect at best a Pregnancy Category D designation or alternatively a Category X designation for Zofran:

> **Pregnancy Category D. If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans**, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: "Pregnancy Category D. See "Warnings and Precautions" section. Under the "Warnings and Precautions" section, **the labeling must state: "[drug] can cause fetal harm when administered to a pregnant woman. . . . If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."**
>
> 21 C.F.R. § 201.57(f)(6)(i)(d) (emphasis added).
>
> **Pregnancy Category X. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction**

> **reports from investigational or marketing experience, or both**, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: "Pregnancy Category X. See 'Contraindications' section." Under "Contraindications," **the labeling must state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman. . . . (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."**

Id. § 201.57(f)(6)(i)(e) (emphasis added).

70. Beginning at least in 1992, GSK had positive evidence of human fetal risk posed by Zofran based more than 200 reports to GSK of birth defects, as well as epidemiology studies, and placental-transfer studies reporting on Zofran's teratogenic risk. GSK has never updated Zofran's labeling to disclose that Zofran can cause fetal harm when administered to a pregnant woman, and GSK has failed to warn of the potential hazards to a fetus arising from Zofran use during pregnancy.

71. The FDA recently promulgated a final rule declaring that, as of June 2015, it will require pharmaceutical manufacturers to remove the current A, B, C, D, or X pregnancy categorization designation from all drug product labeling and instead summarize the risks of using a drug during pregnancy, discuss the data supporting that summary, and describe relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. 79 Fed. Reg. 72064 (Dec. 4, 2014). In promulgating this rule, the FDA "determined that retaining the pregnancy categories is inconsistent with the need to accurately and consistently communicate differences in degrees of fetal risk."

72. In summary, beginning years before Plaintiff was exposed to Zofran, GSK marketed and sold Zofran without adequate warning to healthcare providers and consumers that Zofran was causally associated with an increased risk of birth defects, and that GSK had not adequately tested Zofran to support marketing and promotion it for use in pregnant women. This rendered the warnings accompanying Zofran inadequate and defective.

73. Plaintiff hereby demands that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiff and similarly situated mothers and mothers-to-be, as

GSK's wrongful conduct alleged herein is continuing. Plaintiff further demands that GSK fully and fairly comply, no later than June 2015, to remove the Pregnancy Category B designation from its drug product labeling for Zofran and fully and accurately summarize the risks of using Zofran during pregnancy, fully and accurately describe the data supporting that summary, and fully and accurately describe the relevant information to help health care providers make informed prescribing decisions and counsel women about the risks associated with use of Zofran during pregnancy.

GSK's Fraudulent, Off-Label Promotion of Zofran for the Treatment of Morning Sickness in Pregnant Women

74. At all relevant times, GSK has known that the safety of Zofran for use in human pregnancy has not been established.

75. But with more than six million annual pregnancies in the United States since 1991 and an estimated 70-85% incidence of pregnancy-related nausea, the absence of a prescription medication that was approved by the FDA for pregnancy-related nausea presented an extremely lucrative business opportunity for GSK to expand its sales of Zofran. GSK seized that opportunity, but the effect of its conduct was tantamount to experimenting with the lives of unsuspecting mothers-to-be and their babies in the United States and in this State.

76. After the FDA approved Zofran in 1991, and despite available evidence showing that Zofran presented an unreasonable risk of harm to babies exposed to Zofran prenatally, GSK launched a marketing scheme to promote Zofran to obstetrics and gynecology (Ob/Gyn) healthcare practitioners, among others, as a safe treatment alternative for morning sickness in pregnant women.

77. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) notified GSK that the FDA had become aware of GSK's promotional materials for Zofran that violated the Federal Food Drug and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance." (FDA Ltr. to Michele Hardy, Director, Advertising and Labeling Policy, GSK, Mar. 9 1999.)

78. GSK's promotional labeling under consideration included promotional statements relating the effectiveness of Zofran, such as "Zofran Can," "24-hour control," and other promotional messages. But the promotional labeling failed to present any information regarding the risks associated with use of Zofran.

79. In its March 9, 1999 letter, the FDA directed GSK to "**immediately cease distribution of this and other similar promotional materials for Zofran that contain the same or similar claims without balancing risk information**."

80. GSK blatantly disregarded this mandate by the FDA. For example, in 2002, GSK's marketing materials to Ob/Gyn practitioners emphasized Zofran's "Pregnancy Category B" designation on the very first page of the marketing material, creating a false impression that the safety of use in pregnancy has been established. GSK's materials failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran treatment during pregnancy.

81. GSK's promotion of Zofran for use in pregnancy eventually led to a federal governmental investigation. On July 2, 2012 the Department of Justice announced that GSK "agreed to plead guilty and pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs," which included Zofran among numerous others. *See* DOJ Press Release, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012).

82. Part of GSK's civil liability to the government included payments arising from the facts that: (a) GSK promoted Zofran and disseminated false representations about the safety and efficacy of Zofran concerning pregnancy-related nausea and hyperemesis gravidarum, a severe form of morning sickness; and (b) GSK paid and offered to pay illegal remuneration to health care professionals to induce them to promote and prescribe Zofran.

Plaintiff's Exposure to Zofran

83. Plaintiff Sonya Lampkin is the mother and natural guardian of J.S.

84. To alleviate the symptoms of morning sickness, Plaintiff Sonya Lampkin was prescribed Zofran beginning early in her first trimester of pregnancy with J.S.

85. J.S. was born in 2010.

86. J.S. was diagnosed with a supraventricular tachycardia ("SVT") as a direct and proximate result of her prenatal exposures to Zofran.

87. J.S. was prescribed Digoxin to help with the symptoms of SVT including rapid breathing, shortness of breath, and shallow breathing.

88. There is no history of birth defects in J.S.'s family.

89. Plaintiff Sonya Lampkin was unaware of the dangerousness of Zofran or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during pregnancy.

90. Had Plaintiff Sonya Lampkin and/or her healthcare providers known of the increased risk of birth defects associated with Zofran, she would not have taken Zofran during pregnancy and J.S. would not have been born with congenital malformations.

91. As a direct and proximate result of GSK's conduct, Plaintiff Sonya Lampkin and her son J.S. have suffered and incurred harm including severe and permanent pain and suffering, mental anguish, medical expenses and other economic and noneconomic damages, and will require more constant and continuous medical monitoring and treatment than had they not been exposed to Zofran.

92. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Zofran caused the appreciable harm sustained by her son, J.S. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the injuries at an earlier time. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, the tortious nature of the conduct causing the injuries, until a short time before filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because GSK has misrepresented to the public and to the medical profession that Zofran is safe for use in pregnancy, and GSK has fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action. In all events, the statute of limitations is tolled for claims arising from injuries to minors.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

93. Plaintiff repeats, reiterates and realleges 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.

94. Defendants had a duty to exercise reasonable care, and comply with existing standards of care, 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.

95. DEFENDANTS failed to exercise ordinary care and failed to comply with existing standards of care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that defendants knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

96. Defendants, their agents, servants, and/or employees, failed to exercise ordinary care and failed to comply with existing standards of care in the following acts and/or omissions:

a. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety risks of Zofran for treating pregnant women while promoting the use of Zofran and providing kickbacks to health care professionals to convince health care professionals to prescribe Zofran for pregnancy-related nausea;

b. Marketing Zofran for the treatment of morning sickness in pregnant women without testing it determine whether or not Zofran was safe for this use;

c. Designing, manufacturing, producing, promoting, formulating, creating, and/or designing Zofran without adequately and thoroughly testing it;

d. Selling Zofran without conducting sufficient tests to identify the dangers posed by Zofran to pregnant women;

e. Failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Zofran for pregnant women;

f. Failing to evaluate available data and safety information concerning Zofran use in pregnant women;

g. Advertising and recommending the use of Zofran without sufficient knowledge as to its dangerous propensities to cause birth defects;

h. Representing that Zofran was safe for treating pregnant women, when, in fact, it was and is unsafe;

i. Representing that Zofran was safe and efficacious for treating morning sickness and hyperemesis gravidarum when Defendants were aware that neither the safety nor efficacy for such treatment has been established;

j. Representing that GSK's animal studies in rats and rabbits showed no harm to fetuses, when the data revealed impairment of ossification (incomplete bone growth) and other signs of toxicity;

k. Failing to provide adequate instructions regarding birth defects including cleft palate and cardiac malformations;

l. Failing to accompany Zofran with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Zofran;

m. Failing to include a black box warning concerning the birth defects associated with Zofran;

n. Failing to issue sufficiently strengthened warnings following the existence of reasonable evidence associating Zofran use with the increased risk of birth defects;

o. Failing to advise Plaintiff, her healthcare providers, FDA, and the medical community that neither the safety nor the efficacy of Zofran for treating pregnancy-related nausea has been established and that the risks of the using the drug for that condition outweigh any putative benefit; and

p. Failing to advise Plaintiff, her healthcare providers, FDA, and the medical community of clinically significant adverse reactions (birth defects) associated with Zofran use during pregnancy.

97. Despite the fact that defendants knew or should have known that Zofran significantly increased the risk of birth defects, GSK continued and continue to negligently and misleadingly market, manufacture, distribute and/or sell Zofran to consumers, including Plaintiff.

98. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care, as set forth above.

99. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiff suffered and/or will continue to suffer.

100. Had Plaintiff Sonya Lampkin not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity.

101. As a result of the foregoing acts and omissions, J.S. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

102. Plaintiff Sonya Lampkin also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

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

104. By reason of the foregoing, Plaintiff has been damaged by defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interests, costs herein included, attorney's fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SECOND CAUSE OF ACTION
(NEGLIGENCE PER SE)

105. Plaintiff repeats, reiterates and realleges 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.

106. Defendants had a duty 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.

107. Defendants failed to exercise ordinary care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, 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 of dangerous birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

108. Defendants, their agents, servants, and/or employees, failed to exercise ordinary care and violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.128, in particular.

109. The laws violated by defendants were designed to protect Plaintiff and similarly situated persons and protect against the risks and hazards that have actualized in this case. Therefore, defendants' conduct constitutes negligence per se.

110. Despite the fact that defendants knew or should have known that Zofran significantly increased the risk of birth defects, defendants continued and continue to negligently and misleadingly market, manufacture, distribute and/or sell Zofran to consumers, including Plaintiff.

111. defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of defendants' failure to exercise ordinary care, as set forth above.

112. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiff suffered and/or will continue to suffer.

113. Had Plaintiff Sonya Lampkin not taken Zofran, her baby would not have suffered those injuries and damages as described herein.

114. As a result of the foregoing acts and omissions, J.S. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

115. Plaintiff Sonya Lampkin also has sustained severe emotional distress and suffering as a result defendants' wrongful conduct and the injuries to her child.

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

117. By reason of the foregoing, Plaintiff has been damaged by defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interests, costs herein included, attorney's fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

THIRD CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

118. Plaintiff repeats, reiterates and realleges 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.

119. Zofran was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by defendants and was defective at the time it left defendants' control in that, and not by way of limitation, the drug failed to include adequate warnings, instructions and directions relating to the dangerous risks associated with the use of Zofran to treat pregnancy-related nausea. Zofran also was defective in its design

because the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design. Safe and effective products were available for the purpose for which defendants marketed Zofran in pregnant women, and neither the safety nor the efficacy of Zofran for that purpose had been established.

120. Defendants failed to provide adequate warnings to physicians and users, including Plaintiff, of the increased risk of birth defects associated with Zofran and aggressively promoted the product off-label to doctors, to hospitals, and directly to consumers.

121. Prescribing physicians, health care providers and mothers-to-be, neither knew, nor had reason to know at the time of their use of Zofran of the existence of the aforementioned defects. Ordinary consumers would not have recognized the potential risks or side effects for which defendants failed to include appropriate warnings, and which defendants masked through unbalanced promotion of Zofran specifically for treatment of pregnant women.

122. At all times herein mentioned, due to defendants' off-label marketing of Zofran, the drug was prescribed and used as intended by defendants and in a manner reasonably foreseeable to defendants.

123. As a direct and proximate result of the defective nature of Zofran, J.S. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

124. Plaintiff Sonya Lampkin also has sustained severe emotional distress and suffering as a result defendants' wrongful conduct and the injuries to her child.

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

126. By reason of the foregoing, Plaintiff has been damaged by defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the

level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interests, costs herein included, attorney's fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

FOURTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)
(Against Defendant. GSK only)

127. Plaintiff repeats, reiterates and realleges 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.

128. GSK falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff Sonya Lampkin and her providers, that:

a. Zofran was safe and effective for treating pregnancy-related nausea;

b. Zofran had been adequately tested and studied in pregnant women;

c. Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

d. Zofran's "Pregnancy Category B" designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

129. The representations made by GSK were material, false and misleading.

130. When GSK made these representations, it knew they were false.

131. GSK made these representations with the intent of defrauding and deceiving the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, including Plaintiff and her providers, to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy-related nausea, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff herein.

132. At the time the aforesaid representations were made by GSK and, at the time Plaintiff used Zofran, she was unaware of the falsity of said representations and reasonably believed them to be true.

133. In reliance upon said representations, Plaintiff's prescriber was induced to prescribe Zofran to her, and Plaintiff Sonya Lampkin was induced to and did use Zofran to treat pregnancy-related nausea.

134. GSK knew that Zofran had not been sufficiently tested for pregnancy-related nausea and that it lacked adequate warnings.

135. GSK knew or should have known that Zofran increases expectant mothers' risk of developing birth defects.

136. As a result of the foregoing acts and omissions, J.S. was caused to suffer birth defects that are permanent and lasting in nature, as well as physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

137. Plaintiff Sonya Lampkin also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

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

139. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interests, costs herein included, attorney's fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

FIFTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)
(Against Defendant. GSK only)

140. Plaintiff repeats, reiterates and realleges 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.

141. In representations to Plaintiff's healthcare providers, expectant mothers including Plaintiff and the FDA, GSK fraudulently concealed and intentionally omitted the following material facts:

a. GSK was illegally paying and offering to pay doctors remuneration to promote and prescribe Zofran;

b. Zofran had not (and has not) been tested or studied in pregnant women at all;

c. *in utero* Zofran exposure increases the risk of birth defects;

d. 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;

e. the safety and efficacy of Zofran for treating pregnancy-related nausea has not been established;

f. Zofran is not safe and effective for treating pregnancy-related nausea; and

g. GSK's internal data and information associated Zofran use during pregnancy with birth defects.

142. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran for pregnancy-related nausea was made purposefully, willfully, wantonly, and/or recklessly, to mislead physicians, hospitals and healthcare providers, and expectant mothers including Plaintiff Sonya Lampkin into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

143. GSK knew that physicians, hospitals, healthcare providers and expectant mothers such as Plaintiff had no way to determine the truth behind GSK's concealment and material omissions of facts surrounding Zofran, as set forth herein.

144. Plaintiff and her providers reasonably relied on GSK's promotional statements concerning Zofran's asserted safety and efficacy in pregnant women, from which GSK negligently, fraudulently and/or purposefully omitted material facts.

145. As a result of the foregoing acts and omissions, J.S. was caused to suffer serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

146. Plaintiff Sonya Lampkin also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

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

148. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interests, costs herein included, attorney's fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SIXTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)
(Against Defendant. GSK only)

149. Plaintiff repeats, reiterates and realleges 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.

150. GSK falsely and negligently represented to the medical community and expectant mothers, including Plaintiff and her providers, that:

a. Zofran was safe and effective for treating pregnancy-related nausea;

b. Zofran had been adequately tested and studied in pregnant women;

c. Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

d. Zofran's "Pregnancy Category B" designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

151. The representations made by GSK were, in fact, false and misleading.

152. As a result of the foregoing acts and omissions, J.S. has suffered serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

153. As a result of the foregoing acts and omissions, A.S requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Sonya Lampkin is informed and believes and further alleges that J.S. will in the future be required to obtain further medical and/or hospital care, attention, and services.

154. Plaintiff Sonya Lampkin also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

155. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interests, costs herein included, attorney's fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SEVENTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

156. Plaintiff repeats, reiterates and realleges 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.

157. Defendants expressly warranted that:

a. Zofran was safe and effective for treating pregnancy-related nausea;

b. Zofran had been adequately tested and studied in pregnant women;

c. Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

d. Zofran's "Pregnancy Category B" designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

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

159. Plaintiff and her healthcare providers did rely on the express warranties of the GSK herein.

160. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the defendants for use of Zofran in recommending, prescribing, and/or dispensing Zofran to treat morning sickness.

161. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Zofran was not safe and fit for the use promoted, expressly warranted and intended by GSK, and, in fact, it produced serious injuries to the pregnant women and their babies, which injuries were not accurately identified and disclosed by GSK.

162. As a result of the foregoing acts and omissions, J.S. was caused to suffer serious and dangerous side effects including, life-threatening birth defects, physical pain and mental

anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

163. Plaintiff Sonya Lampkin also has sustained severe emotional distress and suffering as a result defendants' wrongful conduct and the injuries to her child.

164. As a result of the foregoing acts and omissions, J.S. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Sonya Lampkin is informed and believes and further alleges that J.S. will in the future be required to obtain further medical and/or hospital care, attention, and services.

165. By reason of the foregoing, Plaintiff has been damaged by defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interests, costs herein included, attorney's fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

EIGHTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR PARTICULAR USE)

166. Plaintiff repeats, reiterates and realleges 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.

167. Defendants are merchants with respect to goods of the kind Plaintiff received. Defendants impliedly warranted that its product was merchantable. Defendants impliedly warranted that its product was fit for the particular purpose of being used safely in the treatment of pregnancy-related nausea. Plaintiff and her health care providers relied on defendants' skill and judgment when deciding to use defendants' product.

168. Defendants' product was not fit for the ordinary purpose for which such goods were used. It was defective in design and its failure to provide adequate warnings and

instructions, and was unreasonably dangerous. Defendants' product was dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including Plaintiff and her medical providers.

169. Defendants breached its implied warranties because the product was not safe, not adequately packaged and labeled, did not conform to representations defendants made, and was not properly usable in its current form according to the labeling and instructions provided.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interests, costs herein included, attorney's fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants on each of the above-referenced claims and Causes of Action and as follows:

a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

b) For medical, incidental and hospital expenses according to proof;

c) For pre-judgment and post-judgment interest as provided by law;

d) For full refund of all purchase costs of Zofran;

e) For consequential damages in excess of the jurisdictional minimum of this Court;

f) For compensatory damages in excess of the jurisdictional minimum of this Court;

g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;

h) For attorneys' fees, expenses and costs of this action; and

i) For such further and other relief as this Court deems necessary, just and proper.

Dated: 3-4-15

KERSHAW, CUTTER & RATINOFF LLP

By: _____
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