

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION**

**MARQUITA SMILEY, Individually and)
as Parent and Natural Guardian of Z.P.,)
a Minor,)
Plaintiff,)
v.)
GlaxoSmithKline LLC,)
Defendant.)**
_____)

CIVIL ACTION NO. _____

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff, MARQUITA SMILEY, individually and on behalf of her son, Z.P., 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 Z.P. as a result of her prenatal exposures to Zofran and/or its generic bioequivalent, 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 as a result of chemotherapy or radiation treatments in cancer patients.

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 further marketed Zofran during this time as a “wonder drug” for pregnant women, despite having knowledge that GSK had never once undertaken a single study establishing that this powerful drug was safe or effective for pregnant mothers and their growing children *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 establishing the safety and efficacy of Zofran for treating pregnant women before GSK marketed Zofran for the treatment of pregnant women. GSK, in fact, excluded pregnant women from its clinical trials used to support its application for FDA approval of Zofran. In short, GSK simply chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment during pregnancy. GSK avoided conducting these studies and buried any internal analyses of Zofran’s teratogenic potential 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 nationwide fraudulent marketing campaign, Zofran was placed into the hands of unsuspecting pregnant women and in the 2000s became the number one most prescribed drug for treating morning sickness in the United States. These women ingested the drug because they innocently believed that Zofran was an appropriate drug for use in their circumstances. 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. Zofran would never have become the most prescribed morning sickness drug in the United States, and Plaintiff would never have taken Zofran and/or its generic bioequivalent, if GSK had not misleadingly marketed the drug as a safe and efficacious treatment for morning sickness.

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, and further showed that Zofran's active ingredient 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 material 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, including reports of the same congenital anomalies suffered by Z.P. GSK never disclosed these reports to pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological and mechanistic studies that have demonstrated an elevated risk of developing Zofran-induced 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 since at least January 1998.

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. In exchange for GSK's full performance of its criminal plea agreement with the United States and for certain other promises exchanged between GSK and the

United States, the United States agreed not to prosecute GSK criminally for conduct relating to “GSK’s sales, marketing and promotion of . . . Zofran between January 1998 and December 2004.” (Agreement between United States and GSK, pp. 1-2, June 27, 2012.)

8. 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 specifically.

9. GSK’s written agreement with the United States reports GSK’s settlement of 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]”**
- (b) **“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. As the holder of the NDA for Zofran, GSK knew that pharmaceutical companies filing and holding abbreviated new drug applications (“ANDA”) would rely on GSK’s representations to the FDA, physicians and patients that Zofran was safe and effective. GSK also knew that any generic bioequivalent manufacturer must show that “the labeling proposed for the new drug is the same as the labeling approved for the listed drug.” 21 U.S.C. § 355(j)(2)(A)(v). GSK further knew that pharmacies in this state and elsewhere routinely substitute less expensive generic drugs such as ondansetron in place of branded drugs such as Zofran. In other words, GSK knew, or should have known that as long as they held the NDA for Zofran, they were responsible

for the adequacy of the label and warnings for all forms of ondansetron – whether brand name or generic.

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

12. Plaintiff's minor child, Z.P., was born in 2014 with congenital heart and kidney defects after his mother, Plaintiff Marquita Smiley, was prescribed and began taking Zofran and/or its generic bioequivalent beginning early in her first trimester of pregnancy and took it continuously as needed and prescribed throughout her pregnancy to alleviate and prevent the symptoms of morning sickness.

13. According to Z.P.'s treating physician's records, Z.P. was born with multiple congenital anomalies. During Plaintiff Marquita Smiley's pregnancy, Z.P. was diagnosed via ultrasound with a congenital heart defect. After Z.P. was born, echocardiogram analysis showed that Z.P. suffered from congenital heart defects, namely a Hypoplastic Left Heart Syndrome. Z.P. also suffered from a kidney defect.

14. Z.P. was exposed to ondansetron *in utero* during the periods when each of these tissues was forming and susceptible to developmental insult from environmental exposure.

15. According to his treating physicians' records, there is no genetic cause for Z.P.'s condition. Z.P. has no family history of any of the conditions from which he suffers, and his six-year-old sister was born perfectly healthy.

16. Z.P. had to undergo multiple surgeries, including open heart surgery at three days old, open heart transplant at six months, and required extended hospitalization and medical care throughout his first year of life.

17. Had Plaintiff's prescribing physician known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, she would never have prescribed Zofran to Marquita Smiley and Z.P. would never had been injured as described herein.

18. Had Plaintiff known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, she would never have ingested Zofran and/or its generic bioequivalent and Z.P. would never had been injured as described herein.

19. Plaintiff brings claims for compensatory 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 ondansetron.

JURISDICTION AND VENUE

20. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because GSK is a citizen of a state other than the state in which Plaintiff is a citizen.

21. Venue in this judicial district is proper under 28 U.S.C. § 1391 inasmuch as a substantial part of the events or omissions giving rise to the claims occurred in this district.

22. At all times herein mentioned, GSK conducted, and continues to conduct, a substantial amount of business activity and has committed a tort, in whole or in part, in this judicial district. GSK is registered to conduct business in this district, with a Resident Agent located in Montgomery, Alabama and engaged in interstate commerce when they advertised, promoted, supplied, and sold pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial

revenue in this district. Although GSK's plan to misleadingly market Zofran for pregnancy was devised outside this district, it was executed nationwide, including in this district.

PARTIES

23. Plaintiff, Marquita Smiley, is a citizen of the United States. She is the mother and natural guardian of Z.P., who lives with Ms. Smiley. Plaintiff resides in Birmingham, Jefferson County, Alabama.

24. 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.

25. GSK is the successor in interest to Glaxo, Inc. and Glaxo Wellcome 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. GSK continued to be the holder of the NDA for Zofran at all times material to this action.

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

PERTINENT BACKGROUND ON ZOFRAN

27. 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.)

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

29. 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).

30. 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.

31. 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).

32. 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).

33. 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)

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

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

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

Preclinical Studies

40. 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.

41. 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.

42. 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. These preclinical teratogenicity studies in rats and rabbits were stated by the sponsor, GSK, to show no harm to the fetus, but the data also revealed clinical signs of toxicity, premature births, intrauterine fetal deaths, and impairment of ossification (incomplete bone growth).

43. 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.

44. 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 lowerdose groups. The study also reported maternal weight loss in the exposed groups. Developmental retardation in offspring and fetuses were noted – namely, areas of the parietal (body cavity) were not fully ossified, and the hyoid (neck) failed to ossify completely.

45. 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 and labored breathing, which are symptoms 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.

46. 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.”

47. 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

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

49. 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.

50. 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.

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

52. 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.

53. 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

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

55. 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”).

56. 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.

57. 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.

58. 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.

59. 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.

60. The Slone Study investigated the association between the use of ondansetron for nausea and vomiting during pregnancy (NVP) and the risk of specific birth defects by analyzing data from two case-control studies: the Slone Birth Defects Study (BDS) (1997-2013) and the National Birth Defects Prevention Study (NBDPS) (2005-2009). The Slone Epidemiology Center in Boston is continuing its 2012 study of ondansetron and birth defects, periodically releasing results from its updated study. Researchers conclude that off-label use of ondansetron to treat nausea and vomiting during pregnancy (NVP) has been increasing, yet information regarding its safety in pregnancy is inadequate. Further, the outcome of these studies indicated an increased risk of Cleft Palate, Kidney Malformation and Blockage, Hypoplastic Left Heart Syndrome, and Diaphragmatic Hernia in babies born to mothers who used ondansetron during early pregnancy. This analysis included a review of pregnancies in Western Australia from 2002-2005 comparing pregnancy outcomes during that period (96,968 women who did not use ondansetron during pregnancy and 251 women who did use ondansetron during pregnancy) which resulted in outcomes showing a 20% increased risk of a major birth defect amongst children exposed to ondansetron in the first trimester of pregnancy.

61. 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, including, but not limited to, Hypoplastic Left Heart Syndrome. 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**

62. 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).

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

64. 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.*

65. 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).

66. 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. Smiley and her prescribing healthcare provider.

67. 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.

68. By contrast, the U.S. Supreme Court has declared that a generic drug manufacturer cannot unilaterally add to or strengthen a contraindication, warning, precaution or adverse reaction. *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 660 (Ala. 2014) (citing *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (U.S. 2011)).

69. 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. Had GSK done so, the manufacturers of generic bioequivalent versions of Zofran would have been required to make the same additions. *Id.* at 660-661.

70. 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.”

71. 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.

72. 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.

73. 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.”

74. 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 not recommended.”**

75. 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.

76. 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).

77. 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 lifethreatening 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).

78. 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.

79. 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."

80. 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.

81. 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 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**

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

83. 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.

84. At least as early as January 1998, 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 including those in this State, among others, as a safe treatment alternative for morning sickness in pregnant women.

85. In support of its off-label marketing efforts, at least as early as January 1998, GSK offered and paid substantial remuneration to healthcare providers and "thought leaders" to induce them to promote and prescribe Zofran to treat morning sickness.

86. 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.)

87. 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.

88. 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.”**

89. 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.

90. When Zofran was first approved by the FDA to treat cancer patients, GSK’s Oncology Division sales force had primary responsibility for marketing and promoting the drug. Beginning in at least January 1998, GSK set out to expand its Zofran sales to obstetricians and gynecologists by promoting Zofran as an established safe and effective treatment for morning sickness. GSK’s initial strategy in this regard required its sales force to create new relationships with obstetricians and gynecologists by adding them as “new accounts.” While this strategy had

some success, it was inefficient compared to a revised promotional strategy that would enable GSK to leverage its other Division's already established relationships with obstetricians and gynecologists. Thus, GSK's Oncology Division began partnering with GSK's Consumer Healthcare Division to promote Zofran.

91. Specifically, in or about 2001, GSK's Oncology Division finalized a co-marketing agreement with GSK's Consumer Healthcare division under which sales representatives from GSK's Consumer Healthcare division would market Zofran to obstetricians and gynecologists. At the time GSK's Consumer Healthcare sales force already had established relationships with, and routinely called on, obstetricians and gynecologists to promote and provide samples of another GSK product, Tums, specifically for the treatment and prevention of heartburn during pregnancy. GSK's established network for promoting Tums for use in pregnancy afforded it an efficient additional conduit for promoting Zofran for use in pregnancy.

92. GSK's primary purpose in undertaking this co-marketing arrangement was to promote Zofran to obstetricians and gynecologists during GSK's Consumer Healthcare sales force's visits to obstetricians and gynecologists offices. Although some obstetricians and gynecologists performed surgeries and could order Zofran for post-operative nausea, the central focus of GSK's co-marketing effort was to promote Zofran for the much more common condition of morning sickness in pregnancy, and thus increase sales and profits.

93. GSK's Zofran sales representatives received incentive-based compensation that included an annual salary and a quarterly bonus. The bonus amount was determined by each sales representative's performance in the relevant market and whether s/he attained or exceeded quarterly sales quotas. The more Zofran sold by a GSK sales representative or prescribed by a

provider in that representative's sales territory, the greater his or her compensation and other incentives would be.

94. As a result of GSK's fraudulent marketing campaign, the precise details of which are uniquely within the control of GSK, Zofran achieved blockbuster status by 2002 and became the number one most prescribed drug for treating morning sickness in the United States. In 2002, sales of Zofran in the United States totaled \$1.1 billion, while global Zofran sales were approximately \$1.4 billion in 2002.

95. 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).

96. 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.

97. GSK's 2012 civil settlement with the United States covered improper promotional conduct that was part of an overarching plan to maximize highly profitable Zofran sales without due regard to laws designed to protect patient health and safety. Another component of that plan led to a separate \$150 million settlement between GSK and the United States in 2005. In or around 1993, a GSK marketing document sent to all of its sales and marketing personnel nationwide

advised that they should emphasize to medical providers not only the benefits of Zofran but also the financial benefits to the providers by prescribing Zofran. Specifically, “[b]y using a 32 mg bag [of Zofran], the physician provides the most effective dose to the patient and increases his or her profit by \$___ in reimbursement.” GSK’s marketing focus on profits to the prescribers misleadingly aimed to shift prescribers’ focus from the best interests of patients to personal profit. In this regard, GSK marketed Zofran beginning in the 1990s as “convenient” and offering “better reimbursement” to prescribers. GSK detailed this plan in a marketing document for its Zofran premixed IV bag entitled “Profit Maximization – It’s in the Bag.” Upon information and belief, GSK’s conduct in this paragraph continued until the DOJ began investigating it in the early 2000s.

Plaintiff’s Exposures to Ondansetron

98. Plaintiff Marquita Smiley is the mother and natural guardian of Z.P.

99. To alleviate and prevent the symptoms of morning sickness, Plaintiff Marquita Smiley was prescribed Zofran and/or its generic bioequivalent beginning in her first trimester of pregnancy with Z.P. She took the medication as directed and continued Zofran and/or its generic bioequivalent as needed and as prescribed throughout her pregnancy.

100. Z.P. was born in 2014.

101. According to Z.P.’s treating physician’s records, Z.P. was born with multiple congenital anomalies. During Plaintiff Marquita Smiley’s second trimester of pregnancy, Z.P. was diagnosed via ultrasound with a congenital heart defect, namely Hypoplastic Left Heart Syndrome. After Z.P. was born, echocardiogram analysis showed that Z.P. suffered from congenital heart defects, namely a Hypoplastic Left Heart Syndrome. Z.P. also suffered from a kidney defect.

102. Z.P. was exposed to ondansetron *in utero* during the periods when each of these tissues was forming and susceptible to developmental insult from environmental exposure.

103. According to his treating physicians' records, there is no genetic cause for Z.P.'s condition. Z.P. has no family history of any of the conditions from which he suffers. Z.P.'s six year old sister was born healthy and with no defect and Plaintiff Marquita Smiley did not use ondansetron during her earlier pregnancy with Z.P.'s sister.

104. Plaintiff Marquita Smiley was unaware of the dangerousness of ondansetron or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran and/or its generic bioequivalent during pregnancy.

105. Had Plaintiff's prescribing physician known of the increased risk of birth defects associated with ondansetron, and had she not been misled by GSK's promoting the drug's purported safety benefits for use in pregnancy (on which she reasonably relied), she would not have prescribed Zofran/ondansetron to Marquita Smiley and Z.P. would never have been injured as described herein.

106. Had Plaintiff known of the increased risk of birth defects associated with Zofran/ondansetron, and had she not been misled by GSK's promoting the drug's purported safety benefits for use in pregnancy (on which she reasonably relied), Plaintiff would not have taken Zofran/ondansetron and/or its generic bioequivalent and Z.P. would not have been born with congenital malformations.

107. As a direct and proximate result of GSK's conduct, Plaintiff Marquita Smiley and her son Z.P. 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 ondansetron.

108. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that GSK caused the appreciable harm sustained by her son, Z.P. 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/ondansetron 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)

109. 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.

110. GSK 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.

111. GSK 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 GSK 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.

112. GSK, its 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, ondansetron ANDA holders, 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 GSK was 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, ondansetron ANDA holders 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;
- p. Failing to advise Plaintiff, her healthcare providers, FDA, ondansetron ANDA holders and the medical community of clinically significant adverse reactions (birth defects) associated with Zofran use during pregnancy; and
- q. Failing to correct its misrepresentations that the safety and efficacy of Zofran for treating morning sickness had been established.

113. Despite the fact that GSK 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.

114. GSK knew or should have known that consumers such as Plaintiff would foreseeably use Zofran and/or its generic bioequivalent and rely upon representations made by GSK as the holder of the NDA for Zofran.

115. GSK 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.

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

117. Had Plaintiff Marquita Smiley not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a

truthful and non-misleading manner, Plaintiff's physician would have never prescribed Zofran and Ms. Smiley would never have taken the Zofran and/or its generic bioequivalent.

118. As a result of the foregoing acts and omissions, Z.P. 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.

119. Plaintiff Marquita Smiley also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

120. 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 Marquita Smiley 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.

121. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct.

SECOND CAUSE OF ACTION
(NEGLIGENCE PER SE)

122. 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.

123. GSK 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.

124. GSK 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.

125. GSK, its 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.

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

127. Despite the fact that GSK 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.

128. GSK knew or should have known that consumers such as Plaintiff would foreseeably use the Zofran and/or its generic bioequivalent and rely upon representations made by GSK as the holder of the NDA for Zofran.

129. GSK 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.

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

131. Had Plaintiff Marquita Smiley not taken Zofran, her baby would not have suffered those injuries and damages as described herein.

132. As a result of the foregoing acts and omissions, Z.P. 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.

133. Plaintiff Marquita Smiley also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

134. 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 Marquita Smiley 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.

135. 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.

THIRD CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

136. 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.

137. GSK committed actual and constructive fraud. GSK committed actual fraud by misrepresenting material facts on which Plaintiff and her healthcare providers acted. GSK committed constructive fraud by acting contrary to legal or equitable duties, trust, or confidence

upon which Plaintiff relied, and by failing to act, though it should have. GSK's conduct constitutes constructive fraud because GSK breached legal and equitable duties and violated its fiduciary relationships to patients and healthcare providers.

138. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiff and her providers.

139. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiff and her healthcare providers.

140. In violations of existing standards and duties of care, GSK made misrepresentations by means including, but not limited to, advertisements, labeling, marketing, marketing persons, notices, product information and written and oral information provided to patients and medical providers.

141. In violations of existing standards and duties of care, GSK intentionally, knowingly, falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff Marquita Smiley 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.

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

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

144. 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.

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

146. In reasonable reliance upon said representations, Plaintiff's prescriber was induced to prescribe Zofran and/or its generic bioequivalent to her and recommend the drug as safe for treating pregnancy-related nausea, and Plaintiff Marquita Smiley was induced to and did use Zofran and/or its generic bioequivalent to treat pregnancy-related nausea. Had GSK not made the foregoing express and implied false statements about the product, Plaintiff's physician would not have recommended or prescribed Zofran and Plaintiff would not have used the product.

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

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

149. GSK knew or should have known that consumers such as Plaintiff would foreseeably use Zofran and/or its generic bioequivalent and rely upon representations made by GSK as the holder of the NDA for Zofran.

150. As a result of the foregoing acts and omissions, Z.P. 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.

151. Plaintiff Marquita Smiley also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

152. 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 Marquita Smiley 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.

153. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct.

FOURTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

154. 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.

155. In GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiff and her healthcare providers. GSK had exclusive access to material information about the teratogenic risks of Zofran, and GSK knew that neither Plaintiff nor her medical providers could reasonably discover that information.

156. In violations of the existing standards and duties of care, GSK fraudulently concealed and intentionally omitted material facts in representations by means including, but not limited to advertisements, labeling, marketing, marketing persons, notices, product information

and written and oral information provided to patients, medical providers, generic bioequivalent ANDA holders, and the FDA.

157. In violations of the existing standards and duties of care, in representations to Plaintiff's healthcare providers, expectant mothers including Plaintiff, generic bioequivalent ANDA holders 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. independent researchers have reported in peer-reviewed literature that *in utero* Zofran exposure increases the risk of birth defects;
- e. 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;
- f. the safety and efficacy of Zofran for treating pregnancy-related nausea has not been established;
- g. Zofran is not safe and effective for treating pregnancy-related nausea; and
- h. GSK's internal data and information signaled an association between Zofran use during pregnancy with birth defects.

158. 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 Marquita Smiley into reliance, continued use of Zofran and/or its generic bioequivalent, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

159. 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.

160. 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. Had GSK disclosed the material omissions about the product, Plaintiff would not have used Zofran and/or its generic bioequivalent and her providers would not have prescribed Zofran and at a minimum would have communicated to Plaintiff the pregnancy risks and how to avoid them.

161. As a result of the foregoing acts and omissions, Z.P. 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.

162. Plaintiff Marquita Smiley also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

163. 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 Marquita Smiley 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.

164. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct.

FIFTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

165. 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.

166. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiff and her healthcare providers.

167. In violation of the existing standards and duties of care, GSK materially misrepresented and omitted complete and accurate information in Zofran's labeling, advertising, marketing, sales and marketing persons, notices, oral promotional efforts, and product information concerning the nature, character, quality, safety, and proper use of their product. Specifically, these misrepresentations GSK falsely and negligently represented to the medical community and expectant mothers, including Plaintiff and her healthcare providers, include, but are not limited to the following:

- 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.

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

169. Plaintiff and her providers reasonably relied upon GSK's expertise, skill, judgment, and knowledge and upon their express and/or implied warranties that their product was safe, efficacious, adequately tested, of merchantable quality and fit for use during pregnancy. In

justifiable reliance upon these misrepresentations, Plaintiff and her providers were induced to prescribe and use Zofran and/or its generic bioequivalent.

170. Had GSK not made express and implied false statements, or revealed all material information about Zofran, Plaintiff's providers would not have prescribed it and Plaintiff would not have used Zofran and/or its generic bioequivalent.

171. As a result of the foregoing acts and omissions, Z.P. 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.

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

173. Plaintiff Marquita Smiley also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

174. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct.

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 GSK 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 consequential damages in excess of the jurisdictional minimum of this Court;
- e) For compensatory damages in excess of the jurisdictional minimum of this Court;
- f) 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;
- g) For attorneys' fees, expenses and costs of this action; and
- h) For such further and other relief as this Court deems necessary, just and proper.

Dated: July 23, 2015

Respectfully Submitted,

/s/Don McKenna

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