UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

STACY COUGHLIN, Individually and on behalf of L.D., a Minor.,

and

ASHLEY SWANN, Individually and on behalf of V.P., a Minor

Plaintiffs

V.

GLAXOSMITHKLINE LLC,

Defendant

CIVIL ACTION NO.

JUDGE

MAGISTRATE JUDGE

JURY DEMAND

COMPLAINT

Now into Court, through undersigned counsel, come Plaintiffs, Stacy Coughlin, Individually and on behalf of her daughter, L.D., a minor, and Ashley Swann, Individually and on behalf of V.P., a minor, who file this Complaint with Jury Demand and allege as follows:

NATURE OF THE CASE

1. This action is brought on behalf of Plaintiffs Stacy Coughlin, individually and on behalf of her daughter, L.D., and Ashley Swann, individually and on behalf of her daughter, V.P., who seek compensatory and punitive damages, and such other relief as is just and proper arising from the injuries caused to L.D. and V.P. as a result of their prenatal exposure to the prescription drug Zofran, also known as odansetron.

2. Zofran is a drug that was approved by the Food and Drug Administration (hereinafter "FDA") in 1991 to treat severe nausea in cancer patients undergoing chemotherapy and radiation treatments. To date, this remains the only FDA approved use for Zofran.

3. GlaxoSmithKline (hereinafter "GSK") marketed Zofran "off label" as a safe and effective treatment for pregnancy-related nausea and vomiting, commonly called "morning sickness."

4. GSK engaged in this "off label" marketing despite never having conducted a single study on the effects of Zofran on pregnant women or their unborn children. GSK chose not to study Zofran in pregnant women or seek FDA approval before marketing the drug for treatment during pregnancy.

5. As a result, Zofran was prescribed to unsuspecting pregnant women throughout the United States. Pregnant women ingested Zofran because they were led to believe that Zofran was safe to use for the treatment of pregnancy-related nausea. Pregnant women who ingested Zofran had no way of knowing that their use of Zofran increased the risk that their unborn children would develop serious birth defects.

6. At the same time GSK was marketing Zofran to pregnant women, GSK knew that Zofran was unsafe for ingestion by pregnant women. GSK conducted animal studies in the 1980s which revealed evidence of toxicity, intrauterine deaths, and malformations in offspring. These studies also demonstrated 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 information to pregnant women or their physicians.

7. By 1992, GSK had a multitude of evidence linking Zofran to birth defects. GSK received at least 32 reports of birth defects associated with Zofran by 2000, and has received more than 200 such reports to date. Nevertheless, GSK did not disclose the 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 never disclosed this information to pregnant women or their physicians. Instead, GSK sales representatives continued to market and promote Zofran as a drug for pregnancy-related nausea at all times relevant to this case.

8. GSK pled guilty in 2012 to criminal charges brought by the U.S. Department of Justice regarding its "off label" promotion of drugs for uses that were never approved by the FDA. GSK's written agreement with the United States reports GSK's settlement of allegations 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)

9. GSK's fraudulent and unlawful conduct in the marketing and promotion of Zofran as a safe morning sickness drug to pregnant women has caused serious and irreversible damage to innocent children and their families, including Plaintiffs and their minor children L.D. and V.P., herein.

10. GSK negligently and improperly failed to perform sufficient and adequate testing on pregnant women using Zofran during clinical trials. This inadequate testing evinced a callous, reckless, and willful indifference to the health, safety and welfare of pregnant women and their unborn children, including Plaintiffs and their minor child L.D. and V.P., herein.

11. As a result of the foregoing acts and omissions, Plaintiffs' minor children L.D. and V.P. suffered serious and dangerous birth defects caused by exposure to Zofran while *in utero*. L.D.'s injuries include, but are not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), and intermittent tachypnea, which is reflective of congestive heart failure. V.P.'s injuries include, but are not limited to, accelerated ventricular arrhythmia.

12. Therefore, Plaintiffs seeks compensatory and punitive damages, and such other relief as is just and appropriate arising from injuries caused by Plaintiffs' ingestion of Zofran while they were pregnant with their minor children herein.

JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to each Plaintiff individually exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiffs and Defendant GSK.

14. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the Plaintiffs' claims occurred in this District, and because Defendant GSK conducts substantial business in this District.

15. This Court has personal jurisdiction over Defendant GSK because it has done business in the State of Louisiana, has committed a tort in whole or in part in the State of Louisiana, has substantial and continuing contact with the State of Louisiana, and derives substantial revenue from goods used and consumed with the State of Louisiana. Defendant GSK actively advertises, sells, markets, distributes, and/or promotes its pharmaceutical product Zofran to physicians and consumers in the State of Louisiana on a regular and consistent basis.

PARTIES

16. Plaintiff Stacy Coughlin and her minor child, L.D., are citizens and residents of the State of Louisiana, and were citizens and residents of the State of Louisiana at all times relevant to the allegations in this Complaint. Plaintiff's minor child, L.D., upon information and belief, suffered severe personal injuries as a result of Plaintiff's use of Zofran while pregnant with L.D.

17. Plaintiff Ashley Swann and her minor child, V.P., are citizens and residents of the State of Louisiana, and were citizens and residents of the State of Louisiana at all times relevant to the allegations in this Complaint. Plaintiff's minor child, V.P., upon information and belief, suffered severe personal injuries as a result of Plaintiff's use of Zofran while pregnant with V.P.

18. Defendant GlaxoSmithKline (hereinafter "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 as Wilmington, Delaware.

19. 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.

20. Upon information and belief, GSK has transacted and conducted business in the State of Louisiana.

21. Upon information and belief, GSK has derived substantial revenue from goods and products used in the State of Louisiana.

22. Upon information and belief, GSK, expected or should have expected its acts to have consequence within the United States and the State of Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of Louisiana, more particularly.

23. Upon information and belief, and at all relevant times, GSK, was in the business of and did design, develop, research, manufacture, test, advertise, promote, market, sell, and/or distribute the drug Zofran for use by pregnant women as an anti-nausea, "morning sickness" medication.

ZOFRAN SPECIFIC FACTUAL BACKGROUND

24. Zofran is a drug that was approved by the Food and Drug Administration (hereinafter "FDA") in 1991 to treat severe nausea in cancer patients undergoing chemotherapy and radiation treatments. To date, this remains the only FDA approved use for Zofran.

25. The Zofran Prescribing Information as of September 2014 provides as follows:

> **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)

26. Zofran is an anti-emetic (a drug that prevents or treats nausea and vomiting) belonging to a class of anti-emetics called selective serotonin 5HT3 receptor anatagonists. The active ingredient in Zofran is ondansetron hydrochloride, an antagonist at the 5-hydroxytryptamine receptor type 3 (5-HT3).

27. Serotonin triggers nausea and vomiting in the human body. Zofran works by inhibiting the body's serotonin activity.

28. 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).

29. 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)

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

31. In order to lawfully market Zofran for treating morning sickness in pregnant women, GSK is required to adequately test the drug for that purpose (including performing appropriate clinical studies) and to formally submit evidence demonstrating that the drug is safe and effective for that purpose to the FDA. Without obtaining FDA approval to market a drug for the treatment of pregnant women, GSK may not legally market its drug for that purpose.

32. Despite having the resources and capability to perform appropriate studies, GSK has not performed any clinical studies to determine the effect on pregnant women who take Zofran.

33. Further, GSK has not submitted any data to the FDA demonstrating that Zofran is safe and effective for treating pregnancy-related nausea in pregnant women. Rather, GSK has illegally circumvented the FDA-approval process by marketing Zofran for the treatment of pregnancy-related nausea 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.

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

35. 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.

36. 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.

37. 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).

38. **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.

39. **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. The study showed an increase in the number of intra-uterine deaths in the 4 mg/kg group versus lower-dosage 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.

40. **Study No. R10590** was an 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.

41. **Study No. L10649** was an 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."

42. Even assuming that these animal studies do not conclusively reveal evidence of potential harm to a fetus exposed to Zofran, GSK was aware that animal studies are 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. GSK nevertheless went forward with marketing and promoting Zofran to pregnant women.

43. GSK began receiving reports of birth defects associated with the use of Zofran by pregnant women as early as 1992.

44. By 2000, GSK had received at least 32 reports of birth defects associated with Zofran, including reports of congenital heart disease, dysmorphism, intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomaly, congenital musculoskeletal anomalies, and orofacial anomalies, among others.

45. To date, GSK has received more than 200 reports of birth defects in children who were exposed to Zofran while *in utero*. Upon information and belief, the number of such events that were actually reported to GSK comprises only a small fraction of all such events.

46. 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").

47. Each of these studies employs methodologies tending to bias results toward under-reporting the true risk of having a child with a birth defect. Despite this, 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 who ingested Zofran had more than a double risk of having a baby with a congenital heart defect compared to a mother who did not ingest Zofran while pregnant.

48. **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. A total of 608,385 pregnancies between January 2004 and March 31, 2011 were studied. 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 an atrioventricular septal defect.

49. **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.

50. **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 10,492 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.

51. It is clear that since as early as 1992, GSK has been privy to mounting evidence that Zofran poses an unreasonable risk of harm to babies exposed to the drug while *in utero*. 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 pregnant women.

52. Federal law governs GSK's drug labeling obligations for its pharmaceutical products, including Zofran, and federal law requires GSK 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).

53. Federal law also requires GSK to list adverse reactions that occurred with other drugs in the same class as Zofran. *Id.* § 201.57(g).

54. 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.*

55. 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)

56. 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 Plaintiffs and their prescribing healthcare providers.

57. 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.

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

59. 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."

60. GSK has known since at least 1998 based on its off-label promotion and payments to doctors, its obvious 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 of causing birth defects.

61. 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, (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.

62. From 1993 to the present, despite being privy to 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."

63. 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**."

64. In the United States, including Louisiana, GSK has at all relevant times failed to include any warning regarding the risk of birth defects arising from the use of Zofran during pregnancy in Zofran's prescribing information or other product labeling.

65. 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 consists of five letter-categories (A, B, C, D, and X, in order of increasing risk).

66. GSK had the ability, and indeed was required under federal law, to update Zofran's label to reflect at least 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).
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> **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).

67. Beginning at least in 1992, GSK had evidence of human fetal risk posed by Zofran ingestion based on 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.

68. 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."

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

70. Plaintiffs hereby demand that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiffs and other similarly situated mothers and mothers-to-be, as GSK continues to engage in the same wrongful conduct. Plaintiffs further demand that GSK fully and fairly comply, no later than September of 2015, to remove the Pregnancy Category B designation from its drug product labeling for Zofran and fully and accurately summarize the known 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.

CASE SPECIFIC FACTUAL BACKGROUND

a. Plaintiff Stacy Coughlin

71. Plaintiff Stacy Coughlin is the mother and natural guardian of L.D. Plaintiff began using Zofran on or about January 14, 2010, during her first trimester of pregnancy with L.D. Plaintiff ingested Zofran for the purpose of alleviating and preventing pregnancy-related nausea.

72. Plaintiff's physician would not have prescribed Zofran to Plaintiff if he knew of the true risks associated with the use of Zofran.

73. At the time Plaintiff ingested Zofran, she was unaware of the dangers posed by ingesting Zofran during pregnancy, and she was unaware of the fraudulent nature of GSK's marketing of Zofran as a safe drug for the purpose of treating pregnancy-related nausea.

74. Plaintiff would not have elected to use Zofran if she knew of the true risks associated with the use of Zofran. In other words, Plaintiff would not have elected to use Zofran if she had known that Zofran posed a risk of causing birth defects in her unborn child, L.D.

75. L.D. was born on July 15, 2010.

76. As a direct and proximate result of her prenatal exposure to Zofran, L.D. was diagnosed soon after birth with several congenital heart defects, including perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), and intermittent tachypnea, which is reflective of congestive heart failure.

77. There is no known history of birth defects of the type suffered by L.D. in L.D.'s family. Before L.D. was born, Plaintiff gave birth to L.D.'s healthy older brother in 2005 following a pregnancy in which Plaintiff did not ingest Zofran.

78. As a direct and proximate result of GSK's conduct, Plaintiff and her daughter L.D. have suffered and incurred damages, including severe and permanent pain and suffering, mental anguish, medical expenses and other economic and non-economic damages, and will require more medical treatment than had they not been exposed to Zofran.

79. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Zofran caused the appreciable harm sustained by her daughter, L.D. 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 alleged 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.

b. Plaintiff Ashley Swann

80. Plaintiff Ashley Swann is the mother and natural guardian of V.P. Plaintiff began using Zofran in or around February of 2005, during her first trimester of pregnancy with V.P. Plaintiff ingested Zofran for the purpose of alleviating and preventing pregnancy-related nausea.

81. Plaintiff's physician would not have prescribed Zofran to Plaintiff if he knew of the true risks associated with the use of Zofran.

82. At the time Plaintiff ingested Zofran, she was unaware of the dangers posed by ingesting Zofran during pregnancy, and she was unaware of the fraudulent nature of GSK's marketing of Zofran as a safe drug for the purpose of treating pregnancy-related nausea.

83. Plaintiff would not have elected to use Zofran if she knew of the true risks associated with the use of Zofran. In other words, Plaintiff would not have elected to use Zofran if she had known that Zofran posed a risk of causing birth defects in her unborn child, V.P.

84. V.P. was born on August 9, 2005.

85. As a direct and proximate result of her prenatal exposure to Zofran, V.P. was diagnosed soon after birth with accelerated ventricular arrhythmia, a serious heart defect which nearly caused V.P. to die shortly after birth. V.P. required intense and regular medical monitoring and testing for the first five years of her life due to her condition.

86. There is no known history of birth defects of the type suffered by V.P. in V.P.'s family.

87. As a direct and proximate result of GSK's conduct, Plaintiff and her daughter V.P. have suffered and incurred damages, including severe and permanent pain and suffering, mental anguish, medical expenses, and other economic and non-economic damages, that they would not have endured had they not been exposed to Zofran.

88. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Zofran caused the appreciable harm sustained by her daughter, V.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 alleged 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.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

89. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

90. GSK had a duty to exercise reasonable care in the designing, developing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Zofran into the stream of commerce, including but not limited to a duty to assure that the

product would not cause users to suffer unreasonable and dangerous adverse side effects, to properly warn of all risks, and to comply with federal requirements.

91. GSK failed to exercise ordinary care in the designing, developing, 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 the use of GSK by pregnant women could cause significant harm to unborn children, including but not limited to physical injuries of a permanent and disabling nature, physical pain and mental anguish, diminished enjoyment of life, and hospitalization and other medical expenses, and was therefore not safe for use by pregnant women.

92. GSK's negligent acts and/or omissions include, but are not limited to:

a. Producing, manufacturing, formulating, designing, and/or advertising Zofran to pregnant women to treat morning sickness without sufficiently, thoroughly, and/or adequately testing it for that purpose;

b. Selling Zofran to pregnant women without performing sufficient/adequate testing to determine the full range of dangers to pregnant women;

c. Failing to warn Plaintiffs, the general public, healthcare providers, and the FDA of the dangers associated with using Zofran during pregnancy;

d. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and/or use Zofran;

e. Failing to test Zofran and/or failing to adequately, sufficiently and properly test Zofran for use by pregnant women;

f. Negligently advertising and recommending the use of Zofran to Plaintiffs, the general public, and healthcare providers without sufficient knowledge as to its dangerous propensities in pregnant women;

g. Negligently representing that Zofran was safe for use by pregnant women, when, in fact, it was unsafe;

h. Negligently representing that Zofran was equally as safe and effective as other available forms of treatment for morning sickness in pregnant women;

i. Negligently designing Zofran in a manner which was dangerous to users, including Plaintiffs;

j. Negligently manufacturing Zofran in a manner which was dangerous to users, including Plaintiffs;

k. Negligently producing Zofran in a manner which was dangerous to users, including Plaintiffs;

l. Negligently assembling Zofran in a manner which was dangerous to users, including Plaintiffs;

m. Knowingly concealing that Zofran was unsafe, dangerous, and/or non-conforming with FDA regulations from Plaintiffs, the general public, and healthcare providers;

n. Improperly concealing and/or misrepresenting information regarding the risks and dangers posed by using Zofran during pregnancy.

93. Despite the fact that GSK knew or should have known that Zofran significantly increased the risk of birth defects, GSK continued and continues today to manufacture and market Zofran for use by pregnant women and continues to fail to comply with federal requirements.

94. GSK knew or should have known that consumers such as Plaintiffs and their minor children would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

95. It was foreseeable that GSK's product, as designed, would cause serious injury to consumers, including Plaintiffs and their minor children.

96. As a direct and proximate result of GSK's negligence, Plaintiffs and their minor children were caused to suffer serious and dangerous side effects including, but not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure accelerated

ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

97. GSK's conduct evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages. This conduct includes but is not limited to: failing to adequately design, test, and manufacture GSK for use by pregnant women; marketing and distributing Zofran to pregnant women when GSK knew or should have known of the serious health risks it posed to unborn children; and failing to comply with federal requirements.

COUNT II: NEGLIGENCE PER SE

98. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

99. 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.

100. 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.

101. 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.

102. The laws violated by GSK were designed to protect Plaintiffs 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.

103. 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 Plaintiffs.

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

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

106. Had Plaintiffs not taken Zofran, their minor children herein would not have suffered those injuries and damages as described in this Complaint.

107. As a result of the foregoing acts and omissions, Plaintiffs and their minor children herein were caused to suffer serious and dangerous side effects including, but not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure, accelerated ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT III: NEGLIGENT MISREPRESENTATION

108. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

109. GSK falsely and fraudulently represented to pregnant women and the medical and healthcare community, including Plaintiffs and their health care 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.

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

111. GSK knew that the representations were false when it made the representations.

112. 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 Plaintiffs and their health care providers, to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy-related nausea, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety and welfare of Plaintiffs herein.

113. At the time the aforesaid representations were made by GSK and, at the time Plaintiffs used Zofran, they were unaware of the falsity of said representations and reasonably believed them to be true.

114. In reliance upon said representations, Plaintiffs' prescribers were induced to prescribe Zofran to them, and Plaintiffs were induced to, and did use Zofran to treat pregnancy-related nausea.

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

116. GSK knew or should have known that exposure to Zofran increases the risk that children *in utero* will develop birth defects.

117. As a result of the foregoing acts and omissions, Plaintiffs and their minor children herein were caused to suffer serious and dangerous side effects including, but not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure, accelerated ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT IV: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

118. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

119. GSK negligently inflicted severe emotional distress upon the Plaintiffs by their negligent and careless actions, including, but not limited to:

a. Producing, manufacturing, formulating, designing, and/or advertising Zofran to pregnant women to treat morning sickness without sufficiently, thoroughly, and/or adequately testing it for that purpose;

b. Selling Zofran to pregnant women without performing sufficient/adequate testing to determine the full range of dangers to pregnant women;

c. Failing to warn Plaintiffs, the general public, healthcare providers, and the FDA of the dangers associated with using Zofran during pregnancy;

d. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and/or use Zofran;

e. Failing to test Zofran and/or failing to adequately, sufficiently and properly test Zofran for use by pregnant women;

f. Negligently advertising and recommending the use of Zofran to Plaintiffs, the general public, and healthcare providers without sufficient knowledge as to its dangerous propensities in pregnant women;

g. Negligently representing that Zofran was safe for use by pregnant women, when, in fact, it was unsafe;

h. Negligently representing that Zofran was equally as safe and effective as other available forms of treatment for morning sickness in pregnant women;

i. Negligently designing Zofran in a manner which was dangerous to users, including Plaintiffs;

j. Negligently manufacturing Zofran in a manner which was dangerous to users, including Plaintiffs;

k. Negligently producing Zofran in a manner which was dangerous to users, including Plaintiffs;

l. Negligently assembling Zofran in a manner which was dangerous to users, including Plaintiffs;

m. Knowingly concealing that Zofran was unsafe, dangerous, and/or non-conforming with FDA regulations from Plaintiffs, the general public, and healthcare providers;

n. Improperly concealing and/or misrepresenting information regarding the risks and dangers posed by using Zofran during pregnancy.

120. Had Plaintiffs not taken Zofran, they would not have suffered those injuries and damages as described hereinabove.

121. As a result of the foregoing acts and omissions, Plaintiffs and their minor children herein were caused to suffer serious and dangerous side effects including, but not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure, accelerated ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT V: FRAUDULENT MISREPRESENTATION

122. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

123. GSK falsely and fraudulently represented to pregnant women and the medical and healthcare community, including Plaintiffs and their 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.

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

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

126. 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 Plaintiffs and their health care 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 Plaintiffs herein.

127. At the time the aforesaid representations were made by GSK and, at the time Plaintiffs used Zofran, they were unaware of the falsity of said representations and reasonably believed them to be true.

128. In reliance upon said representations, Plaintiffs' prescribers were induced to prescribe Zofran to them, and Plaintiffs were induced to and did use Zofran to treat pregnancy-related nausea.

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

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

131. As a result of the foregoing acts and omissions, Plaintiffs and their minor children herein were caused to suffer serious and dangerous side effects including, but not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure, accelerated ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT VI: FRAUDULENT CONCEALMENT

132. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

133. In representations to Plaintiffs' healthcare providers, expectant mothers including Plaintiffs 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.

134. 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 Plaintiffs into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

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

136. Plaintiffs and their 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.

137. Plaintiffs also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their minor children herein.

138. As a result of the foregoing acts and omissions, Plaintiffs and their minor children herein were caused to suffer serious and dangerous side effects including, but not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure,

accelerated ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT VII: BREACH OF EXPRESS WARRANTY

139. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

140. GSK expressly warranted that Zofran was a safe and effective product to be used by pregnant women for treating pregnancy-related nausea, that Zofran had been adequately tested and studied in pregnant women, that Zofran use during pregnancy did not increase the risk of bearing children with birth defects, and that Zofran's Category B designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

141. GSK did not disclose the material fact that Zofran use by pregnant women creates an unreasonable risk of serious side effects, including birth defects and intrauterine death, which were not warned about by GSK. The representations regarding Zofran's purported safety were not justified by the performance of Zofran.

142. Members of the consuming public, including consumers like Plaintiffs and their healthcare provider(s), were intended beneficiaries of the warranty.

143. Plaintiffs and their healthcare provider(s) reasonably relied on GSK's express representations pertaining to Zofran's purported safety.

144. GSK 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 pregnant women and their babies, which injuries were not accurately identified and disclosed by GSK.

145. Zofran did not conform to GSK's express representations regarding its purported safety because it caused serious injury to Plaintiffs when used as recommended and directed, and these risks were not disclosed to Plaintiffs or their healthcare providers.

146. As a direct and proximate result of GSK's breach of warranty, Plaintiffs and their minor children herein were caused to suffer serious and dangerous side effects including, but not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure, accelerated ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT VIII: BREACH OF IMPLIED WARRANTY

147. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

148. When GSK designed, developed, manufactured, marketed, sold, and/or distributed Zofran for use by consumers like Plaintiffs, GSK knew of the use for which Zofran was intended and impliedly warranted the product to be of merchantable quality and safe for use in the treatment of pregnancy-related nausea, and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

149. Plaintiffs and their physicians reasonably relied upon GSK's representations regarding Zofran's purported merchantable quality and that it was safe for use by pregnant women to treat pregnancy-related nausea, and reasonably relied upon GSK's implied warranty, including that Zofran was in compliance with all federal requirements.

150. Contrary to GSK's implied warranty, Zofran was not of merchantable quality or safe for use by pregnant women to treat pregnancy-related nausea, because the product was defective, as described herein, and it failed to comply with federal requirements.

151. As a direct and proximate result of GSK's breach of warranty, Plaintiffs and their minor children herein were caused to suffer serious and dangerous side effects including, but not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure, accelerated ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT IX: STRICT PRODUCTS LIABILITY

152. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

153. Zofran was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by GSK and was defective at the time it left GSK's 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 GSK marketed Zofran in pregnant women, and neither the safety nor the efficacy of Zofran for that purpose had been established.

154. GSK failed to provide adequate warnings to physicians and users, including Plaintiffs, 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.

155. 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 GSK failed to include appropriate warnings, and which GSK masked through unbalanced promotion of Zofran specifically for treatment of pregnant women.

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

157. As a direct and proximate result of the defective nature of Zofran, Plaintiffs' minor children herein were 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 potential need for lifelong medical treatment, monitoring and/or medications.

158. Plaintiffs have also sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their minor children herein.

159. As a result of the foregoing acts and omissions, Plaintiffs and their minor children herein were caused to suffer serious and dangerous side effects including, but not limited to, perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure, accelerated ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT X: LOUISIANA PRODUCTS LIABILITY ACT

160. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

161. At all times material to this action, GSK was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Zofran.

162. At all times material to this action, Zofran was expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including Plaintiffs herein, without substantial change in the condition in which it was sold.

163. At all times material to this action, Zofran was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by GSK in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Zofran contained manufacturing defects which rendered the subject product unreasonably dangerous for use by pregnant women;

b. Zofran's manufacturing defects occurred while the product was in the possession and control of GSK;

c. Zofran was not made in accordance with GSK's specifications or performance standards; and

d. Zofran's manufacturing defects existed before it left the control of GSK.

164. The subject product manufactured and/or supplied by GSK was defective in construction or composition in that, when it left the hands of GSK, it deviated in a material way from GSK's manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. In particular, the product is not safe for use by pregnant women, has numerous and serious side effects and causes severe and permanent

injuries. The product was unreasonably dangerous in construction or composition as provided by La. R.S. 9:2800.55.

165. The subject product manufactured and/or supplied by GSK was defective in design in that, an alternative design exists that would prevent serious side effects and severe and permanent injury to pregnant women and their unborn children. The product was unreasonably dangerous in design as provided by La. R.S. 9:2800.56.

166. The subject product manufactured and/or supplied by GSK was unreasonably dangerous because GSK did not provide an adequate warning about the use of Zofran by pregnant women. At the time the subject product left GSK's control, it possessed a characteristic that may cause damage to pregnant women and their unborn children, and GSK failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product. The product is not safe, has numerous and serious side effects, and causes severe and permanent injuries. The product was unreasonably dangerous because of inadequate warning as provided by La. R.S. 9:2800.57.

167. The subject product manufactured and/or supplied by GSK was unreasonably dangerous because it did not conform to an express warranty made by GSK regarding the product's safety and fitness for use. GSK express warranty that Zofran was safe for use by pregnant women to treat pregnancy-related nausea induced Plaintiffs to use the product, and Plaintiffs' damages were proximately caused because GSK's express warranty was untrue. The product was unreasonably dangerous because of nonconformity to express warranty as provided by La. R.S. 9:2800:58.

168. As a result of the foregoing acts and omissions, Plaintiffs and their minor children herein were caused to suffer serious and dangerous side effects including, but not limited to,

perimembranous ventricular septal defect (VSD), which required surgery to correct, atrial septal defect (ASD), intermittent tachypnea, which is reflective of congestive heart failure, accelerated ventricular arrhythmia, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

PRAYER FOR RELIEF

Plaintiffs respectfully request judgment against GSK on each of the above counts as follows:

(a) Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other noneconomic damages in an amount to be determined at trial of this action;

(b) Economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages, including, but not limited to, all damages sustained as a result of the injury in an amount to be determined at trial of this action;

(c) Punitive and exemplary damages for the wanton, willful, fraudulent, and reckless acts of Defendant GSK, which demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiffs, in an amount sufficient to punish Defendant GSK and deter future similar conduct;

(d) Pre-judgment and post-judgment interest as provided by law;

(e) Plaintiffs' attorney fees;

(f) Plaintiffs' costs of the proceedings; and

(g) Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all counts and as to all issues and allegations presented herein.

DATED: June 8, 2015

Respectfully Submitted,

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