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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ROBIN ZGURSKI, STANLEY ZGURSKI, and S.Z.

Plaintiff,

v.

GLAXOSMITHKLINE LLC, MCKESSON CORPORATION, and DOES 1-100,

Defendants.

Case No.

COMPLAINT FOR DAMAGES

(1) Negligence;
(2) Negligence Per Se;
(3) Strict Products Liability;
(4) Intentional Misrepresentation;
(5) Concealment;
(6) Negligent Misrepresentation;
(7) Breach Of Express Warranty;
(8) Breach Of Implied Warranty;
(9) Violation Of Cal. Bus. & Prof. Code §§ 17200, *Et Seq.* And 17500 *Et Seq.*; and
(10) Loss of Consortium.

JURY DEMAND

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiffs, Robin and Stanley Zgurski, individually and on behalf of their son, S.Z., a minor, ("Plaintiffs"), who by and through the undersigned counsel hereby submit this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK") and McKesson Corporation ("McKesson") (collectively, "Defendants") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to S.Z. as a result of Mrs. Zgurski's prenatal exposures to the prescription drug Zofran® (ondansetron hydrochloride), also marketed in its generic form as ondansetron. In support of this Complaint, Plaintiffs allege the following:

I. 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 did this despite having knowledge that such representations were utterly false, as GSK had never once undertaken a single clinical study to examine the safety and effects of this powerful drug on a pregnant mother or her growing child in utero. Unlike another anti-nausea prescription drug available on the market – which is FDA-approved in the United States for treating morning sickness in pregnant women –GSK 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, because the delay occasioned by undertaking the studies would have hampered its marketing of Zofran® and decreased profits by potentially linking the drug to serious birth defects. GSK's conduct was in violation of the FDA's regulations, which are

intended to protect the public health by assuring safety, efficacy and security of drugs, among others things, used on adults and children, including those in utero.

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

5. By contrast, GSK knew that Zofran® was unsafe for ingestion by expectant mothers. In the 1980s, GSK conducted animal studies which revealed evidence of toxicity, intrauterine deaths and malformations in offspring, and further showed that Zofran's active ingredient transferred through the placental barrier in pregnant mammals to their fetuses. A later study conducted in humans confirmed that ingested Zofran® readily crossed the human placenta barrier and exposed fetuses to substantial concentrations. GSK did not disclose this information to pregnant women or their physicians.

6. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with the use of Zofran®. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date. GSK never disclosed these reports to pregnant women or their physicians.

7. In addition, scientists have conducted large-scale epidemiological studies that have demonstrated an elevated risk of developing birth defects such as those suffered in this case. GSK has not disclosed this to pregnant women or their physicians. Instead, GSK sales representatives specifically marketed and promoted Zofran® as a morning sickness drug throughout the relevant time periods discussed herein.

8. 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.

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

10. 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]"**

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.)

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

12. In 2005, Plaintiff Mrs. Zgurski became pregnant with S. Z. and began taking Zofran in her first trimester to alleviate and prevent the symptoms of morning sickness.

13. In January 2006, S.Z. was born with a bilateral cleft lip and palate.

14. S.Z. was exposed to Zofran *in utero* during the periods when his lips and palate were forming and susceptible to developmental insult.

15. Now at just nine years of age, S.Z. has been through multiple surgeries and countless visits with various physicians and specialists. He underwent his first intervention within his first few weeks of life and had surgery before he was even one year old. He has had and continues to have difficulty eating, speaking, and hearing. His birth defects have impaired his development in a variety of ways and interfered with his enjoyment of life both at home and at school.

16. As a direct and proximate result of GSK's conduct, Mr. and Mrs. Zgurski and S.Z. have suffered and incurred harm including severe and permanent pain and suffering, mental anguish, medical expenses and other economic and noneconomic damages, and S.Z. will require

more constant and continuous medical monitoring and treatment than had he not been exposed to Zofran.

17. S.Z. has no family history of cleft lip or palate.

18. Mrs. Zgurski was unaware of the dangerousness of Zofran or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during pregnancy.

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

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

II. JURISDICTION AND VENUE

21. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and the action is between citizens of different states.

22. This Court has personal jurisdiction over Defendants, because, among other reasons, they have significant contacts with this district by virtue of doing business within this judicial district.

23. McKesson's principal place of business is San Francisco, California, located within this judicial district.

24. 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, 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.

25. 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.

III. INTRADISTRICT ASSIGNMENT

26. Pursuant to Local Rule 3-5(b) and (d), assignment to the San Francisco Division is proper, because a substantial part of the events or omissions giving rise to the claims occurred in this division.

IV. PARTIES

27. Mr. and Mrs. Zgurski, husband and wife, are the mother and father and natural guardians of S.Z., who lives with them. Plaintiffs are domiciled in the State of Florida.

28. 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.

29. 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.

30. At all relevant times, GSK conducted business in the States of California, Florida, Pennsylvania and West Virginia and has derived substantial revenue from products, including Zofran, sold in these states.

31. McKesson is a Delaware corporation with its principal place of business in San Francisco, California. Plaintiffs are informed and believe that McKesson was involved in the

manufacture, distribution, marketing, sale, labeling and design of Zofran as detailed below. Specifically, McKesson is the 16th largest industrial corporation in America, with over $800 billion in revenue every year. McKesson's own website states that "McKesson is everywhere" in healthcare. McKesson is the sole supplier of numerous pharmaceuticals to both the largest pharmacies and drug suppliers in the nation including pharmacies such as Wal-Mart, Safeway, Valu-Rite, and the smallest independent and community pharmacies. Upon information and belief, McKesson marketed, sold and distributed the Zofran taken by Mrs. Zgurski. At all times herein mentioned, McKesson was the actor engaged in the acts herein alleged, acting through its agents and employees, and at all times, the actions and omissions asserted in this pleading were committed by agents or employees acting within the purpose and scope of said agency and employment.

V. PERTINENT BACKGROUND ON ZOFRAN

32. 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.)

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

34. 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).

35. 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.

36. Since before GSK began selling Zofran, GSK has known that serotonin also regulates developmental processes that are critical to normal embryonic development. Impeding serotonin signaling during embryonic development can increase the risk of developmental insult to the body's tissues that depend on uninhibited serotonin signaling, including the lips and palate.

37. 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).

38. 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).

39. 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)

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

41. 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.

42. 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.

43. 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.

44. 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.

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

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

1. Preclinical Studies

46. 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.

47. 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.

48. 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).

49. 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.

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

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

52. 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."

53. 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.

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

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

55. 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.

56. 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.

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

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

3. Evidence That Zofran Can Cause Cleft Palates.

59. Since before GSK began selling Zofran, GSK has known serotonin regulates developmental processes that are critical to normal embryonic development. Impeding serotonin signaling during embryonic development can increase the risk of developmental insult to those fetal tissues that depend on uninhibited serotonin signaling, including the palate.

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

61. An epidemiologic study by Marlene Anderka, et al., titled, "Medications Used to Treat Nausea and Vomiting of Pregnancy and the Risk of Selected Birth Defects," (January 1, 2013) ("Anderka Study") reports an increased risk between mothers who took ondansetron during pregnancy and an incidence of cleft palates in their children. The purpose of the Anderka study

was to examine whether nausea and vomiting during pregnancy, and the medications proscribed to treat that nausea and vomiting, were associated with various birth defects. Data was collected by identifying women whose infants had birth defects and interviewing the parents. Of those who completed the interview, 821 had infants born with cleft palate. In particular, the Anderka Study found that taking ondansetron during pregnancy doubles the odds that the child would be born with cleft palate. The study used data from the National Birth Defects Prevention Study ("NBDPS"), and excluded infants with clefts that were secondary to another defect, or who had a parent or sibling with the same defect. Other confounding factors were controlled for, including inter alia, the mother's age, race-ethnicity, education, parity, smoking habits, previous miscarriages and use of folic acid. The Anderka Study showed a more than two-fold increase in cleft palates for children of women who took ondansetron versus those whose mothers did not.

4. 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 Mrs. Zgurski 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. 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.

69. 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."

70. At least as of 1998, GSK knew well from its off-label promotion and payments to doctors, 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.

71. 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.

72. 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."

73. 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.**"

74. In the United States, 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.

75. 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).

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

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

21 C.F.R. § 201.57(f)(6)(i)(d) (emphasis added).

> **Pregnancy Category X. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both**, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy

> are available), the labeling must state: "Pregnancy Category X. See `Contraindications' section." Under "Contraindications," **the labeling must state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman. . . . (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.**"

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

77. 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.

78. The FDA recently promulgated a final rule declaring that, as of June 2015, it will begin requiring 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."

79. In summary, beginning years before Mrs. Zgurski and S.Z. were 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.

80. Plaintiffs hereby demand that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiffs and similarly situated families and mothers-to-be, as

GSK's wrongful conduct alleged herein is continuing. Plaintiffs further demand that GSK promptly, 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.

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

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

82. 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.

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

84. 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.)

85. 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.

86. 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.**"

87. 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.

88. 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).

89. 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.

90. 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 improperly aimed to shift prescribers' priorities 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.

6. S.Z.'s Exposure to Zofran and Related Injuries

91. Plaintiff Mrs. Zgurski is the mother and natural guardian of S.Z.

92. In 2005, Plaintiff's OB/GYN prescribed Zofran for Mrs. Zgurski during her first trimester of pregnancy with S.Z. to alleviate and prevent symptoms of morning sickness.

93. S.Z. was exposed to Zofran in utero during the periods when each of the relevant tissues of his lips and palate were forming and susceptible to developmental insult from environmental exposure.

94. S.Z. was born in 2006.

95. S.Z. was diagnosed with bilateral cleft lip and palate at or around the time of birth.

96. As a result of these injuries, S.Z. has undergone multiple interventions and surgeries, including Nasoalveolar Molding (NAM) at just a few weeks old.

97. Within weeks of birth, S.Z. had a natal tooth extraction and ear tubes placed.

98. At seven months, S.Z. underwent cleft lip and nose repair surgery during which myringotomy tubes (a.k.a. tympanostomy tubes or pressure equalizing (PE) tubes) were placed.

99. Shortly thereafter, S.Z had a surgical palate repair, followed by pharyngeal flap—all when he was less than three years old.

100. Subsequently, S.Z underwent nasal reconstruction surgery.

101. In addition to all the surgeries, S.Z. has also suffered hearing loss, orthodontic issues and severe speech development problems, requiring additional treatments, therapy and interventions.

102. Throughout his childhood, S.Z.'s speech has been difficult to understand, causing him significant frustration and distress.

103. S.Z. continues to be monitored and will need additional interventions and treatments in the future. His next surgery has already been scheduled early in 2016.

104. S.Z. has no family history of cleft lip or palate.

105. Mrs. Zgurski was unaware of the dangerousness of Zofran or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during pregnancy.

106. Had Mrs. Zgurski and/or her healthcare providers known of the increased risk of birth defects associated with Zofran, and had they not been misled by GSK's promoting the drug's purported safety benefits for use in pregnancy (on which they reasonably relied), she would not have taken Zofran during pregnancy and S.Z. would not have been born with congenital malformations.

107. As a direct and proximate result of GSK's conduct, Plaintiffs have suffered and incurred harm including severe and permanent emotional and physical pain and suffering, mental anguish, medical expenses and other economic and noneconomic damages, and S.Z. will require more constant and continuous medical monitoring and treatment than had she not been exposed to Zofran.

108. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting and having reason to learn and discover that Zofran caused the appreciable harm sustained by their son, S.Z. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the injuries at an earlier time. Plaintiffs did not suspect, nor did Plaintiff have reason to suspect the cause of S.Z.'s injuries, nor the tortious nature of the conduct causing the injuries, until a short time before filing of this action.

109. Additionally, Plaintiffs were 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 Plaintiffs to discover a potential cause of action.

110. In all events, the statute of limitations is tolled for claims arising from injuries to minors.

FIRST CAUSE OF ACTION
Negligence

111. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

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

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

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

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

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

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

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

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

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

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

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

i. Representing that Zofran was safe and efficacious for treating morning sickness and hyperemesis gravidarum when 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 Plaintiffs, their healthcare providers, FDA, and the medical community that neither the safety nor the efficacy of Zofran for treating pregnancy-related nausea has been established and that the risks of the using the drug for that condition outweigh any putative benefit; and

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

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

116. Reasonable manufacturers and distributers under the same or similar circumstances would have warned of the dangers presented by Zofran, or instructed on the safe use of Zofran.

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

118. Defendants' negligence was the proximate cause and substantial factor in causing of Plaintiffs' injuries, harm and economic loss, which they suffered and/or will continue to suffer.

119. Had Mrs. Zgurski not taken Zofran, S.Z. would not have suffered those injuries and damages as described herein with particularity.

120. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as well as the need for lifelong medical treatment, monitoring and/or medications. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

121. As a result of perceiving their son, S.Z.'s injuries, Mr. and Mrs. Zgurski suffered serious emotional distress. Mr. and Mrs. Zgurski witnessed S.Z.'s injuries and treatment resulting from S.Z.'s exposure to Zofran. Although Mr. and Mrs. Zgurski were unaware at the time of S.Z.'s diagnosis and surgery that Zofran had caused the injury, Defendants' wrongful conduct was a substantial factor in causing Mr. and Mrs. Zgurski's serious emotional distress.

122. By reason of the foregoing, Plaintiffs and S.Z. have been damaged by Defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose

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

SECOND CAUSE OF ACTION
(Negligence Per Se)

123. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

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

125. Defendants failed to exercise ordinary care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that Defendants 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, embarrassment, loss of self-esteem, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

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

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

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

130. Defendants' negligence was the proximate cause and substantial factor of Plaintiffs' injuries, harm and economic loss, which Plaintiffs suffered and/or will continue to suffer.

131. Had Mrs. Zgurski not taken Zofran, S.Z. would not have suffered the injuries and damages as described herein.

132. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as well as the need for lifelong medical treatment, monitoring and/or medications. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

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

THIRD CAUSE OF ACTION
(Strict Products Liability—Design Defect And Failure To Warn)

134. Plaintiffs hereby incorporate by reference all previous paragraphs, as though alleged fully in this Cause of Action.

135. Defendants designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed Zofran into the stream of commerce. Zofran was defective at the time it left Defendants' control in that, and not by way of limitation, the drug failed to include adequate warnings, instructions and directions relating to the dangerous risks associated with the use of Zofran to treat pregnancy-related nausea. The Zofran sold to Mrs. Zgurski 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, failed to perform as safely as an ordinary consumer would expect when used, and the benefits of the design and burden on Defendants to prevent harm did not outweigh the risk of danger and the gravity of the harm that was posed Zofran's defective design.

136. Safe and effective products were available for the purpose for which Defendants marketed Zofran in pregnant women, and neither the safety nor the efficacy of Zofran for that purpose had been established.

137. Defendants failed to provide adequate warnings to physicians and users, including Mrs. Zgurski, 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.

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

139. Zofran was expected to and did reach Plaintiffs and Plaintiffs' physicians without substantial change in their condition as manufactured, distributed, and sold by Defendants.

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

141. The Zofran that was manufactured, distributed, and sold by Defendants to Plaintiffs was in a defective condition that was unreasonably and substantially dangerous to any users or ordinary consumers of the drug for pregnancy-related nausea, such as Plaintiffs. Such ordinary consumers, including Plaintiffs, would not and could not have recognized or discovered the potential risks and side effects of Zofran.

142. Defendants' design, manufacture, marketing, promotion, defense and sale of Zofran was a substantial factor in causing Plaintiffs' injuries, as described herein.

143. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as well as the need for lifelong medical treatment, monitoring and/or medications. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

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

FOURTH CAUSE OF ACTION
(Intentional Misrepresentation)
(Against Defendant GSK only)

145. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

146. GSK falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Mrs. Zgurski 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.

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

148. When GSK made these representations, it knew they were false, or made the representations recklessly, without regard for their truth.

149. 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 Mrs. Zgurski and her providers, to recommend, prescribe, dispense and/or

purchase Zofran to treat pregnancy-related nausea, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiffs herein.

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

151. Plaintiffs and Plaintiffs' physicians justifiably relied to their detriment on GSK's intentional and fraudulent misrepresentations as set out above. This reliance was a substantial factor in and proximately caused the injuries and damages described in this Complaint.

152. In reasonable reliance upon said representations, Mrs. Zgurski's prescribers were induced to prescribe Zofran to her, and Mrs. Zgurski was induced to and did use Zofran to treat pregnancy-related nausea.

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

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

155. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as well as the need for lifelong medical treatment, monitoring and/or medications. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

156. By reason of the foregoing, Plaintiffs and S.Z. have been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, justifying an award of punitive damages.

FIFTH CAUSE OF ACTION
(Concealment)
(Against Defendant GSK only)

157. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

158. In representations to Mrs. Zgurski's healthcare providers, expectant mothers including Mrs. Zgurski 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.

159. 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 Mrs. Zgurski into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

160. Mrs. Zgurski and her providers did not know the concealed facts described above.

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

162. Mrs. Zgurski 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.

163. Had GSK disclosed the material facts described above, Mrs. Zgurski reasonably would not have taken Zofran.

164. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as well as the need for lifelong medical treatment, monitoring and/or medications. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

165. GSK's concealment was a substantial factor in causing Plaintiffs' injuries.

166. By reason of the foregoing, Plaintiffs and S.Z. have been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, so as to indicate a flagrant disregard of the rights and safety of others, justifying an award of punitive damages.

SIXTH CAUSE OF ACTION
(Negligent Misrepresentation)
(Against Defendant GSK only)

167. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

168. GSK falsely and negligently represented to the medical community and expectant mothers, including Mrs. Zgurski 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.

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

170. GSK had no reasonable grounds for believing the aforementioned representations were true when made to the medical community and expectant mothers, including Mrs. Zgurski and her providers.

171. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as well as the need for lifelong medical treatment,

monitoring and/or medications. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

172. By reason of the foregoing, Plaintiffs and S.Z. have 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 flagrant disregard of the rights and safety of others, justifying an award of punitive damages.

SEVENTH CAUSE OF ACTION
(Breach Of Express Warranty)
(Against Defendant GSK only)

173. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

174. Defendants expressly warranted that:

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

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

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

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

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

176. Mrs. Zgurski and her healthcare providers did rely on the express warranties made by GSK herein.

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

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

179. Through sale of Zofran, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

180. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses, as well as the need for lifelong medical treatment, monitoring and/or medications. Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

181. By reason of the foregoing, Plaintiffs and S.Z. have 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 flagrant disregard of the rights and safety of others, justifying an award of punitive damages.

EIGHTH CAUSE OF ACTION
(Breach Of Implied Warranty Of Merchantability And Fitness For Particular Use)

182. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

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

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

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

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

186. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses, as well as the need for lifelong medical treatment, monitoring and/or medications. Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

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

NINTH CAUSE OF ACTION
(Violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.* and §§ 17500, *et seq.*)

188. Plaintiffs hereby incorporate by reference all previous paragraphs, as though alleged fully in this Cause of Action.

189. Plaintiffs bring this cause of action pursuant to California Business & Professions Code §17204, in their individual capacities, and not on behalf of the general public.

190. California Business & Professions Code §17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

191. The acts and practices described in Paragraphs 1 through 91 above were and are likely to mislead the general public, were conducted in California and elsewhere, and therefore constitute unfair business practices within the meaning of Business & Professions Code

§17200. The acts of untrue and misleading advertising and marketing set forth in the preceding paragraphs are incorporated by reference and are, by definition, violations of Business & Professions Code §17200. This conduct includes, but is not limited to:

a. Representing to Plaintiff, Plaintiff's physicians and the general public that Zofran was safe, fit and effective for morning sickness during pregnancy, knowing that said representations were false, and concealing from the Plaintiff, Plaintiff's physicians and the general public that Zofran had a serious propensity to cause birth defects;

b. Engaging in marketing and promotional efforts to create the image, impression and belief by consumers, physicians and others that Zofran was safe for use during pregnancy to treat morning sickness, even though GSK knew this to be false, and even though GSK had no reasonable grounds to believe this to be true;

c. Purposely downplaying and understating the health hazards and risks associated with Zofran;

d. Failing to conduct sufficient testing of Zofran;

e. Withholding important safety information and critical product information from the FDA, medical community and consumers;

f. Continuing to promote the use of the Zofran to physicians despite knowing that there were increased risks of birth defects;

g. Failing to provide adequate warnings regarding the dangerous risks of using Zofran during pregnancy; and

h. Actively, knowingly, and deceptively concealing its knowledge of its product's dangerous properties and life-threatening risks.

192. These practices constitute unlawful, unfair and fraudulent business acts or practices, within the meaning of California Business & Professions Code §17200, as well as unfair, deceptive, untrue and misleading advertising as prohibited by California Business & Professions Code §17500.

193. As a result of their conduct described above, GSK has been and will be unjustly enriched.

194. Plaintiffs, pursuant to California Business & Professions Code §17203, seek an order of this court compelling Defendants to disgorge the monies collected and profits realized by them as a result of their unfair business practices.

195. Plaintiffs also seek injunctive relief pursuant to California Business & Professions Code §§ 17204 and 17535. Specifically, Plaintiffs demand that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiffs and similarly situated mothers and mothers-to-be. Plaintiffs have further demanded that GSK promptly, fully and fairly comply with the FDA's December 4, 2014 final rule referenced above and 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.

TENTH CAUSE OF ACTION
(Loss Of Consortium)

196. Plaintiffs repeat, reiterate and reallege 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.

197. Defendants' negligent and wrongful conduct caused substantial physical injury to their minor child, S.Z.

198. As a result, Plaintiffs have been deprived of services, society, companionship, comfort, love, and solace.

199. As a result, Plaintiffs have also expended reasonable costs for medical care and treatment, lost earnings and lost the ability to earn money in the future resulting from the need to care or provide for S.Z.

200. Plaintiffs seek all damages available against Defendants on account of their loss of their son's consortium under Florida or other applicable law.

DEMAND FOR JURY TRIAL

Plaintiffs demand 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, Plaintiffs demand judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

a. For general (non-economic) damages according to proof at the time of trial in a sum in excess of the jurisdictional minimum of this Court;

b. For special (economic) damages according to proof at the time of trial;

c. For pre-judgment interest as provided by law;

d. For disgorgement of all revenue that Defendants obtained through design, promotion, marketing, manufacture, sale and administration of Zofran;

e. 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;

f. For attorneys' fees, expenses and costs of this action; and

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

Dated: November 6, 2015

Respectfully submitted,

By: */s/ Elizabeth J. Cabraser*
Elizabeth J. Cabraser

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**Pro hac vice* application anticipated