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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT OF THE CENTRAL DISTRICT OF CALIFORNIA

MARIA ABOITES, individually and as Guardian ad Litem for G.A., a minor Plaintiffs, v. GLAXOSMITHKLINE, LLC, and DOES 1-10 Defendants.	CIVIL ACTION NO.: 5:15-cv-01780 COMPLAINT JURY DEMANDED

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiffs, G.A. a minor, individually, and her mother, Maria Aboites, individually, (together, "Plaintiffs"), who by and through the undersigned counsel hereby submit this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "Defendant") for compensatory damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiff G.A. as a result of her prenatal exposures to the prescription drug Zofran®, also known as ondansetron. In support of this Complaint, Plaintiffs allege the following:

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JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

2. Venue is proper in this district pursuant to 28 U.S.C. §1391, et seq., because a substantial part of the events giving rise to this claim occurred in California and this district.

PARTIES

3. Plaintiff, G.A. (D.O.B. 10/22/12), is a citizen of the United States. She is the minor daughter of Plaintiff Aboites. Plaintiff G.A. resides in Victorville, California with her mother. Plaintiff G.A. requests that this Court appoint her mother, Maria Aboites, as Guardian ad Litem for G.A. Plaintiff's Guardian ad Litem petition is filed concurrently herewith.

4. Plaintiff, Maria Aboites, is a citizen of the United States. She is the mother and natural guardian of G.A. Plaintiff Aboites resides in Victorville, California.

5. 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.

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

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

8. DOES 1-10 are unknown Defendants who worked with GSK to place the at-issue product into the stream of commerce as distributors, packagers, or sellers.

INTRODUCTION

9. 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.

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

11. Although the only FDA approval for this drug was for seriously ill patients, GSK marketed Zofran "off label" since at least January 1998 as an established safe and effective treatment for the very common side effect of a normal pregnancy - pregnancy-related nausea and vomiting - otherwise known as "morning sickness." GSK further marketed Zofran during this time as a "wonder drug" for pregnant women, despite having knowledge that GSK had never once undertaken a single study establishing that this powerful drug was safe or effective for pregnant mothers and their growing children *in utero.* Unlike another anti-nausea prescription drug available on the market – which is FDA-approved in the United States for treating morning sickness in pregnant women – GSK never conducted a single clinical trial establishing the safety and efficacy of Zofran for treating pregnant women before GSK marketed Zofran for the treatment of pregnant women. GSK, in fact, excluded pregnant women from its clinical trials used to support its application for FDA approval of Zofran. In short, GSK simply chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment during pregnancy. GSK avoided conducting these studies and buried any internal analyses of Zofran's teratogenic potential because they would have hampered its marketing of Zofran and decreased profits by linking the drug to serious birth defects. GSK's conduct was tantamount to using expectant mothers and their unborn children as human guinea pigs.

12. As a result of GSK's nationwide fraudulent marketing campaign, Zofran was placed into the hands of unsuspecting pregnant women and in the 2000s became the number one most prescribed drug for treating morning sickness in the United States. These women ingested

the drug because they innocently believed that Zofran was an appropriate drug for use in their 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. Zofran would never have become the most prescribed morning sickness drug in the United States, and Plaintiff would never have taken it, if GSK had not misleadingly marketed the drug as a safe and efficacious treatment for morning sickness.

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

14. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date, including reports of the same congenital anomalies suffered by G.A. GSK never disclosed these reports to pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological and mechanistic studies that have demonstrated an elevated risk of developing Zofran-induced birth defects such as those suffered in this case. GSK has not disclosed this material information to pregnant women or their physicians. Instead, GSK sales representatives specifically marketed and promoted Zofran as a morning sickness drug since at least January 1998.

15. In 2012, GSK pled guilty to criminal charges lodged by the United States of America, through the Department of Justice, for its "off-label" promotion of its drugs for uses never approved by the FDA. In exchange for GSK's full performance of its criminal plea agreement with the United States and for certain other promises exchanged between GSK and the United States, the United States agreed not to prosecute GSK criminally for conduct relating

to "GSK's sales, marketing and promotion of . . . Zofran between January 1998 and December 2004." (Agreement between United States and GSK, pp. 1-2, June 27, 2012.)

16. Around the same time, however, GSK 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.

17. GSK's civil settlement 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.)

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

19. Plaintiff G.A. was born in 2012 with numerous congenital facial defects, including cleft palate and cleft lip, after her mother, Plaintiff Maria Aboites, was prescribed and began taking Zofran beginning in her first trimester of pregnancy and took it continuously from then through her second trimester to alleviate and prevent the symptoms of morning sickness. As a result of her condition, G.A. has been subjected to two surgeries thus far in her short life to correct her cleft palate and cleft lip.

20. G.A. was exposed to Zofran *in utero* during the periods when each of the tissues responsible for forming the lip and palate were forming and were susceptible to developmental insult from environmental exposure.

21. There is no known genetic cause for G.A.'s condition. There exists no family history for of any of the conditions from which G.A. suffers. Indeed, G.A.'s older brother

was born healthy and vibrant after Ms. Aboites carried him for a full-term pregnancy during which she did not ingest any Zofran.

22. Had Plaintiff Aboites 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.

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

PERTINENT BACKGROUND ON ZOFRAN

24. 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**
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> 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*.)

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

26. 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).

27. 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.

28. 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).

29. 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).

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

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

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

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

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

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

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

32. 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.

33. 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.

34. 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.

35. 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.

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

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

Preclinical Studies

37. 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.

38. 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.

39. 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).

40. 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.

41. 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.

42. 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 are symptoms of congenital heart defects, and dilated pupils were observed in the 15 mg/kg/day group. Body weight, gestational duration and fetal examinations were reported as normal, but "slight retardation in skeletal ossification" was noted in the offspring.

43. 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."

44. 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. And yet that is precisely what GSK did.

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

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

46. 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.

47. 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.

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

49. The most commonly reported birth defects arising from Zofran use during pregnancy and reported to GSK have been congenital heart defects, orofacial defects, intrauterine death, stillbirth and severe malformations in newborns were frequently reported.

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

There Is an Increased Risk of Cleft Palates in Children Born to Mothers Who Took Ondasetron During Pregnancy

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

52. 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.***

53. In summary, since at least 1992, GSK has had mounting evidence showing that Zofran presents an unreasonable risk of harm to babies who are exposed to the drug during pregnancy. GSK has been aware that Zofran readily crosses human placental barriers during

pregnancy. GSK has also been aware that the animal studies of Zofran cannot reliably support an assertion that Zofran can be used safely or effectively in pregnant women. Since 1992, GSK has received hundreds of reports of major birth defects associated with prenatal Zofran exposure. GSK also has had actual and/or constructive knowledge of the epidemiological studies reporting that prenatal Zofran exposure can more than double the risk of developing congenital heart defects. As alleged below, GSK not only concealed this knowledge from healthcare providers and consumers in the United States, and failed to warn of the risk of birth defects, but GSK also illegally and fraudulently promoted Zofran to physicians and patients specifically for the treatment of morning sickness in pregnancy women.

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

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

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

56. 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.*

57. 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).

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

59. 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.

60. 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.

61. 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."

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

63. 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.

64. 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."

65. 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**."

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

67. 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).

68. 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).

69. 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.

70. 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."

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

72. Plaintiffs Aboites and G.A. hereby demand that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiff Aboites and similarly situated mothers and mothers-to-be, as GSK's wrongful conduct alleged herein is continuing. Plaintiffs

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

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

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

74. 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, which before its patent expiration in 2006 was one of the most expensive drugs available in the U.S. market. 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 Commonwealth.

75. At least as early as January 1998, despite available evidence showing that Zofran presented an unreasonable risk of harm to babies exposed to Zofran prenatally, GSK launched a marketing scheme to promote Zofran to obstetrics and gynecology (Ob/Gyn) healthcare practitioners including those in this State, among others, as a safe treatment alternative for morning sickness in pregnant women.

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

77. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) notified GSK that the FDA had become aware of GSK's

promotional materials for Zofran that violated the Federal Food Drug and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance." (FDA Ltr. to Michele Hardy, Director, Advertising and Labeling Policy, GSK, Mar. 9 1999.)

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

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

80. GSK disregarded this mandate by the FDA. For example, GSK's marketing as materials as early as 2000 in widely circulated in obstetrician and gynecology trade journals over-emphasized Zofran's "Pregnancy Category B" designation as an imprimatur of safeness for use in pregnancy on the very first page of the marketing material and without adequate risk information. This created a false impression on the part of busy healthcare practitioners that the safety of use in pregnancy has been established. GSK's materials failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran treatment during pregnancy.

81. When Zofran was first approved by the FDA to treat cancer patients, GSK's Oncology Division sales force had primary responsibility for marketing and promoting the drug. Beginning in at least January 1998, GSK set out to expand its Zofran sales to obstetricians and gynecologists by promoting Zofran as an established safe and effective treatment for morning sickness. GSK's initial strategy in this regard required its sales force to create new relationships with obstetricians and gynecologists by adding them as "new accounts." While this strategy had some success, it was inefficient compared to a revised promotional strategy that would enable GSK to leverage its other Division's already established relationships with obstetricians and

gynecologists. Thus, GSK's Oncology Division began partnering with GSK's Consumer Healthcare Division to promote Zofran.

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

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

84. GSK's Zofran sales representatives received incentive-based compensation that included an annual salary and a quarterly bonus. The bonus amount was determined by each sales representative's performance in the relevant market and whether s/he attained or exceeded quarterly sales quotas. The more Zofran sold by a GSK sales representative or prescribed by a provider in that representative's sales territory, the greater his or her compensation and other incentives would be.

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

86. 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).

87. 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.

88. 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 personal nationwide advised that they should emphasize to medical providers not only the benefits of Zofran but also the financial benefits to the providers by prescribing Zofran. Specifically, "[b]y using a 32 mg bag [of Zofran], the physician provides the most effective dose to the patient and increases his or her profit by $___ in reimbursement." GSK's marketing focus on profits to the prescribers misleadingly aimed to shift prescribers' focus from the best interests of patients to profit personally. In this regard, GSK marketed Zofran beginning in the 1990s as "personal" 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.

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Plaintiffs' Exposures to Zofran

89. Plaintiff Maria Aboites is the mother of Plaintiff G.A.

90. To alleviate and prevent the symptoms of morning sickness, Plaintiff Aboites was prescribed Zofran beginning in her first trimester of pregnancy with G.A., and she continued Zofran use through her second trimester.

91. G.A. was born on October 10, 2012.

92. At her birth, G.A. was diagnosed with congenital orofacial defects including a cleft palate and a cleft lip as a direct and proximate result of her prenatal exposures to Zofran.

93. G.A. was exposed to Zofran *in utero* during the periods when the tissues responsible for the lip and palate were forming and were susceptible to developmental insult from environmental exposure.

94. There is no known genetic cause for G.A.'s condition. She has no family history of any of the conditions from which she suffers. In addition, G.A. has an older brother who was born healthy and vibrant after Ms. Aboites carried him for a full-term pregnancy during which she did not ingest any Zofran.

95. Plaintiff Maria Aboites was unaware and could not reasonably become aware of the dangerousness of Zofran and of the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during pregnancy.

96. Had Plaintiff Maria Aboites and her prescribers 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), Plaintiff would not have taken Zofran during pregnancy and G.A. would not have been born with congenital malformations.

97. As a direct and proximate result of GSK's conduct, Plaintiff Maria Aboites and her daughter, Plaintiff G.A., have suffered and incurred harm including severe and permanent pain and suffering, mental anguish, medical expenses and other economic and noneconomic damages, and will require more constant and continuous medical monitoring and treatment than had they not been exposed to Zofran.

98. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that GSK's wrongful conduct caused the appreciable harm sustained by G.A. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful conduct that caused the injuries at an earlier time. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, the tortious nature of the conduct causing the injuries, until a short time before filing of this action. 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. In all events, the statute of limitations is tolled for claims arising from injuries to minors.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

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

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

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

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

(i) 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 and financial incentives to health care professionals to convince health care professionals to prescribe Zofran for pregnancy-related nausea;

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

(iii) Designing, manufacturing, producing, promoting, formulating, creating, and/or designing Zofran without adequately and thoroughly testing it;

(iv) Selling Zofran without conducting sufficient tests to identify the dangers posed by Zofran to pregnant women;

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

(vi) Failing to evaluate available data and safety information concerning Zofran use in pregnant women;

(vii) Advertising and recommending the use of Zofran without sufficient knowledge as to its dangerous propensities to cause birth defects;

(viii) Representing that Zofran was safe for treating pregnant women, when, in fact, it was and is unsafe;

(ix) 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;

(x) 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;

(xi) Failing to provide adequate instructions regarding birth defects including cleft palate and cardiac malformations;

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

(xiii) Failing to include a black box warning concerning the birth defects associated with Zofran;

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

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

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

(xvii) Failing to correct its misrepresentations that the safety and efficacy of Zofran for treating morning sickness had been established.

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 Plaintiff Aboites.

104. GSK knew or should have known that consumers such as Plaintiff Aboites 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 Plaintiff suffered and/or will continue to suffer.

106. Had Plaintiff Maria Aboites not taken Zofran, Plaintiff G.A. would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a truthful and non-misleading manner, Ms. Aboites would never have taken Zofran.

107. As a result of the foregoing acts and omissions, Plaintiff G.A. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental

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

108. Plaintiffs Maria Aboites and G.A. also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to G.A.

109. As a result of the foregoing acts and omissions, Plaintiff G.A. requires and will require more health care and services and did incur medical, health, incidental and related expenses.

110. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct.

SECOND CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

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

112. 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.

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

114. Prescribing physicians, health care providers and mothers-to-be, neither knew, nor had reasonable 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.

115. 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.

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

117. Plaintiffs Aboites and G.A. also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to G.A.

118. As a result of the foregoing acts and omissions, Plaintiff G.A. requires and will require more health care and services and did incur medical, health, incidental and related expenses.

119. By reason of the foregoing, Plaintiffs Aboites and G.A. 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 disregard of the rights and safety of others, justifying an award of punitive damages.

THIRD CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

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

121. GSK committed actual and constructive fraud. GSK committed actual fraud by misrepresenting material facts on which Plaintiff and her healthcare providers acted. GSK committed constructive fraud by acting contrary to legal or equitable duties, trust, or confidence upon which Plaintiff relied, and by failing to act, though it should have. GSK's conduct

constitutes constructive fraud because GSK breached legal and equitable duties and violated its fiduciary relationships to patients and healthcare providers.

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

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

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

125. In violations of existing standards and duties of care, GSK intentionally, knowingly, falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff Maria Aboites and her providers, that:

(i) Zofran was safe and effective for treating pregnancy-related nausea;

(ii) Zofran had been adequately tested and studied in pregnant women;

(iii) Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

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

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

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

128. GSK made these representations with the intent of defrauding and deceiving the public in general, and the medical and healthcare community in particular, including Plaintiff and her providers, to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy-related nausea.

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

130. In reasonable reliance upon said representations, Plaintiff Aboites' prescribers were induced to prescribe Zofran to her and recommend the drug as safe for treating pregnancy-related nausea, and Plaintiff Aboites was induced to and did use Zofran to treat pregnancy-related nausea. Had GSK not made the foregoing express and implied false statements about the product, Plaintiff Aboites would not have used the product and her medical providers would not have administered it and recommended it as safe.

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

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

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

134. Plaintiffs Aboites and G.A. also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to G.A.

135. As a result of the foregoing acts and omissions, Plaintiffs require and will require more health care and services and did incur medical, health, incidental and related expenses.

136. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct.

FOURTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

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

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

139. In violations of the existing standards and duties of care, GSK fraudulently concealed and intentionally omitted material facts in representations by means including, but not limited to advertisements, labeling, marketing, marketing persons, notices, product information and written and oral information provided to patients, medical providers, and the FDA.

140. In violations of the existing standards and duties of care, in representations to Plaintiff Aboites' healthcare providers, expectant mothers including Plaintiff Aboites and the FDA, GSK fraudulently concealed and intentionally omitted the following material facts:

(i) GSK was illegally paying and offering remuneration and promoting financial incentives to providers to encourage them to promote and prescribe Zofran;

(ii) GSK had not and has not conducted any studies establishing the safety or efficacy of Zofran treatment in pregnant women;

(iii) *in utero* Zofran exposure increases the risk of birth defects;

(iv) independent researchers have reported in peer-reviewed literature that *in utero* Zofran exposure increases the risk of birth defects;

(v) 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;

(vi) the safety and efficacy of Zofran for treating pregnancy-related nausea has not been established;

(vii) Zofran is not safe and effective for treating pregnancy-related nausea; and

(viii) GSK's internal data and information signaled an association between Zofran use during pregnancy and birth defects.

141. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran for pregnancy-related nausea misled physicians,

hospitals and healthcare providers, and expectant mothers including Plaintiff Maria Aboites and her providers into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

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

143. Plaintiff Aboites and her healthcare providers reasonably relied on GSK's promotional statements concerning Zofran's asserted safety and efficacy in pregnant women, from which GSK negligently, fraudulently and/or purposefully omitted material facts. Had GSK disclosed the material omissions about the product, Plaintiff Aboites would not have used the product and her providers would not have prescribed it, or, at a minimum, would have communicated to Plaintiff the risks of ingesting Zofran during pregnancy.

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

145. Plaintiffs Aboites and G.A. also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to G.A.

146. As a result of the foregoing acts and omissions, Plaintiff G.A. requires and will require more health care and services and did incur medical, health, incidental and related expenses.

147. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct.

FIFTH CAUSE OF ACTION (STATE DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION VIOLATIONS)

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

149. GSK engaged in trade and commerce within the State of California.

150. GSK's violation of express warranties and misrepresentations constitutes a violation of the Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750-1785. GSK's failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

151. As described herein, GSK represented that its product had characteristics, uses, and benefits that it did not have.

152. As described herein, GSK represented that its product was of a particular standard, quality, and grade that they either knew or should have known was not of the standard, quality, or grade described.

153. GSK failed to provide accurate disclosures of all material information before Plaintiff and her providers transacted to use GSK's product.

154. GSK's willful and knowing withholding of important safety information and critical product information constitutes a violation of the Consumer Legal Remedies Act.

155. GSK actively, knowingly, and deceptively concealed their knowledge of its product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

156. GSK engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

157. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally they were unethical and unscrupulous, and caused substantial injury to consumers. GSK engaged in an unconscionable course of action.

158. GSK willfully, wantonly, recklessly, and with gross negligence, engaged in the conduct described herein, which they knew was deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

159. GSK is liable to Plaintiffs for all statutory, direct and consequential damages, and fees and costs, resulting from this breach.

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 GSK on each of the above-referenced claims and Causes of Action and as follows:

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

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

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

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

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

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

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

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

Dated September 1, 2015

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