UNITED STATES DISTRICT COURT OF THE DISTRICT OF MASSACHUSETTS

Janet Seper and Charles Beckenstein, Individually and as Parents and Natural Guardians of Z.B., a Minor, Plaintiffs, v. GlaxoSmithKline LLC, Defendant.	CIVIL ACTION NO.: COMPLAINT JURY DEMANDED

COMPLAINT AND JURY DEMAND

COME NOW Plaintiffs, Janet Seper and Charles Beckenstein, individually and on behalf of their daughter, Z.B., 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" or "Defendant") for compensatory damages and such other relief deemed just and proper arising from the injuries to Z.B. as a result of Plaintiff Janet Seper's prenatal exposure to the prescription drug Zofran®. In support of this Complaint, Plaintiffs allege the following.

PARTIES

1. Plaintiff, Janet Seper is a citizen of the United States who resides in Tampa, Florida. Janet is the parent of Z.B., who is now eleven years old, and brings this lawsuit on her behalf.

2. Plaintiff, Charles Beckenstein is a citizen of the United States who resides in Tampa, Florida. Charles is the parent of Z.B. who is now eleven years old, and brings this lawsuit on her behalf.

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

4. 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.

5. The claims herein are brought on behalf of minor plaintiff Z.B., who suffered birth defects as a result of the Plaintiff Janet Seper's ingestion of the anti-nausea drug, Zofran, which was developed and marketed by Defendant GSK.

JURISDICTION AND VENUE

6. This case is being directly filed in MDL No. 2657 in the District of Massachusetts as provided by 28 U.S.C. § 1407 and pursuant to the Case Management Order No. 6 dated December 17, 2015 in MDL No, 2657, which allowed for direct filing of Zofran actions in this District.

7. A substantial part of the events or omissions giving rise to the claims occurred in the Middle District of Florida and pursuant to 28 U.S.C. § 1391, the Middle District of Florida is a proper venue. Absent Case Management Order No. 6 in MDL No. 2657, plaintiffs would have filed this case in the Middle District of Florida.

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

9. The United States District Court, District of Massachusetts has supplemental jurisdiction over any remaining common law and state claims pursuant to 28 U.S.C. § 1367.

10. Venue in this judicial district is proper under 28 U.S.C. § 1391 because GSK engaged in continuous and systematic business in the Commonwealth of Massachusetts; GSK is

registered to conduct business in the Commonwealth of Massachusetts with a Resident Agent located in Boston, Massachusetts; and GSK owns, operates, and maintains a major research and development facility in Boston, Massachusetts. Further, GSK engages in interstate commerce where it advertises, promotes, supplies, and sells pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public in Massachusetts and derives substantial revenue from its products sold in Massachusetts.

GENERAL AND INTRODUCTORY ALLEGATIONS

11. Zofran is a powerful drug developed by GSK to treat patients who suffering severe nausea from chemotherapy or radiation treatment in cancer patients.

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

13. GSK did not seek FDA approval for and the FDA did not approve Zofran to be administered to pregnant women suffering pregnancy-related nausea, which is commonly known and referred to as "morning sickness".

14. Although the FDA only approved this drug for seriously ill patients, GSK marketed Zofran "off label" since at least January 1998 as an established, safe and effective treatment for "morning sickness" in pregnant women, which is a common side effect of a normal pregnancy. 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 marketing it for the treatment of pregnant women. GSK, in fact, excluded pregnant women from its clinical trials that were submitted to the FDA to support its application for FDA approval.

15. As a result of GSK's nationwide fraudulent marketing campaign, Zofran was prescribed for and taken by unsuspecting pregnant women and, in the 2000s, became the most

prescribed drug for treating morning sickness in the United States. These women ingested the drug because they innocently believed that Zofran was safe for use during pregnancy and were not aware 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 Janet Seper would never have taken it, if GSK had not misleadingly marketed the drug as a safe and efficacious treatment for morning sickness.

16. GSK in fact knew or should have known 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 of the drug. GSK did not disclose this material information to pregnant women or their physicians.

17. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date, including reports of the same congenital anomalies suffered by Z.B. 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 did not disclose 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.

18. 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 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.)

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

20. 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.)

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

22. Upon information and belief, Plaintiffs' minor child, Z.B., was born in 2004 with congenital defects after her mother, Plaintiff Janet Seper, began taking Zofran, beginning in her first trimester of pregnancy, to alleviate the symptoms of morning sickness.

23. Upon information and belief, two days after Z.B. was born, it became apparent that Z.B. had heart problems. Z.B. was subsequently diagnosed with a ventricular septal defect ("VSD").

24. Z.B. was exposed to Zofran *in utero* during the periods when these tissues were forming and susceptible to developmental insult from environmental exposure.

25. Z.B. has no family history of any of the conditions from which she suffers.

26. Z.B. has undergone corrective surgery for her VSD. Her birth defects put her at risk of future corrective surgery and impair her ability to develop fully and enjoy her childhood and life thereafter.

27. Had Plaintiff Janet Seper 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 have been injured as described herein.

PERTINENT BACKGROUND ON ZOFRAN

28. 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.)

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

30. 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).

31. 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.

32. 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).

33. 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).

34. 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)

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

36. 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.

37. 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.

38. 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.

39. 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.

40. At all relevant times, GSK was in the business of and designed, researched, manufactured, tested, packaged, labeled, advertised, promoted, marketed and distributed Zofran.

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

Preclinical Studies

41. 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.

42. 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.

43. 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).

44. 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

45. 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.

46. 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.

47. 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."

48. 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.

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

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

50. 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.

51. 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.

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

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

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

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

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

56. An epidemiologic study by Marlene Anderka, et a., titled *Medications Used to Treat Nausea and Vomiting of Pregnancy and the Risk of Selected Birth Defects* (Jan. 1, 2013)

(the "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 prescribed 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 odansentron 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 whose clefts were secondary to other defects or who had a parent or sibling with the same defect. The study controlled for other confounding factors, including mother's age, race-ethnicity, education, parity, smoking habits, previous miscarriages, and use of folic acid, inter alia. The Anderka Study showed a more than two-fold increase in cleft palates for children of women who took ondansentron versus those whose mothers did not.

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

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

59. The Pasternak Study included data from the Danish National Birth Registry and examined the use of Zofran during pregnancy and risk of adverse fetal outcomes. Adverse fetal outcomes were defined as: spontaneous abortion, stillbirth, any major birth defect, pre-term delivery, low birth weight, and small size for gestational age. There were 608,385 pregnancies between January 2004 and March 31, 2011 examined. The unexposed group was defined as women who did not fill a prescription for ondansetron during the exposure time window. The exposure time window was defined as the first 12-week gestational period. Notably, the median fetal age at first exposure to Zofran was ten weeks, meaning that half of the cases were first exposed to Zofran after organogenesis (organ formation). This characteristic of the study led to an under-reporting of the actual risk of prenatal Zofran exposure. The study's supplemental materials indicated that women taking Zofran during the first trimester, compared to women who did not take Zofran, were 22% more likely to have offspring with a septal defect, 41% more likely to have offspring with a ventricular septal defect and greater than four-times more likely to have offspring with atrioventricular septal defect.

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

61. The Danielsson Study investigated risks associated with Zofran use during pregnancy and risk of cardiac congenital malformations from data available through the Swedish

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

62. 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 cleft palates and congenital heart defects. As alleged below, GSK not only concealed this knowledge from healthcare providers and consumers in the United States, and failed to warn of the risk of birth defects, but GSK also illegally and fraudulently promoted Zofran to physicians and patients specifically for the treatment of morning sickness in pregnant women.

GSK's Failures to Warn Regarding Zofran

63. 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."

64. 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.

65. 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.

66. 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."

67. This statement is false and misleading because it fails to account for animal studies conducted by or on behalf of GSK after the launch of Zofran in the U.S. that reported dose-related birth defects among animals exposed to ondansetron prenatally. Moreover, this statement is negated by GSK's affirmatively marketing Zofran as a safe and effective treatment for pregnancy related nausea and vomiting.

68. The Product Monographs for Zofran in Canada and Europe states "the safety of ondansetron for use in human pregnancy has not been established," and "the use of ondansetron in pregnancy is not recommended." GSK negligently, recklessly or deliberately failed to include such language in its marketing materials and labeling in the United States.

69. GSK's misleading marketing of Zofran as a safe and effective treatment for pregnancy related nausea and vomiting created an unreasonable increased risk of birth defects in children exposed prenatally to Zofran. In view of GSK's marketing of Zofran specifically for pregnancy related nausea and vomiting, and its knowledge of widespread GSK-intended use of the drug for this purpose, the birth defect risks were foreseeable to GSK.

70. GSK breached its duties under state law to take reasonable steps to prevent these foreseeable and intended risks in multiple ways, as discussed below.

71. GSK has at all relevant times failed to correct its misrepresentations that Zofran is a safe and effective treatment for pregnancy related nausea.

72. GSK has at all relevant times failed to correct its misrepresentations that Zofran is a safe and effective treatment prophylactic treatment for the prevention of morning sickness.

73. As soon as GSK began representing that Zofran was and effective for treating pregnancy related nausea and vomiting, GSK had a duty to:

a. Establish a pregnancy registry and recommend that each pregnant patient using the drug be enrolled in a pregnancy registry so that the health outcomes of their children;

b. Perform adequate testing including preclinical and adequate and well-controlled clinical studies to assess the safety and efficacy of the drug from treating pregnancy related nausea;

c. Describe the human studies and GSK's available data on the effect of the prenatal exposure to Zofran on children;

d. Disclose its knowledge that independent human studies have confirmed that Zofran ingested during pregnancy readily crosses a pregnant mother's barrier and exposed fetuses to substantial concentrations, and for longer durations than the mother's exposure;

e. Disclose its knowledge that Zofran has been shown to inhibit the human embryo's serotonin activity, and that such serotonin activity regulates developmental processes that are essential to normal embryonic development;

f. Disclose the hundreds of reports of birth defects associated with Zofran and drugs with related mechanisms of action of which GSK has actual and constructive knowledge;

g. Correct its misrepresentation that Zofran is safe and effective for treating pregnancy related nausea and vomiting by disclosing the independent literature establishing that the safety Zofran for use in pregnancy has not been established;

h. Correct its misrepresentation that Zofran is safe and effective for treating pregnancy related nausea and vomiting by sending letters to prescribers and sponsoring Continuing Medical Education programs disclose that neither the safety nor the efficacy of Zofran for treating pregnancy related nausea and vomiting has been established; and

i. Correct its misrepresentation that Zofran was a safe and effective prophylactic treatment for preventing morning sickness.

74. 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).

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

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

77. 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).

78. 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.

79. GSK thus had the ability and obligation to add warnings, precautions and adverse reactions to the product labeling for Zofran without prior approval from the FDA. GSK failed to do so. Had GSK done so, the manufacturers of generic bioequivalent versions of Zofran would have made the same additions.

80. At least as of 1998, GSK knew well from its misleading 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 to treat morning sickness in pregnant women and that such usage was associated with a clinically significant risk or hazard – birth defects.

81. 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) the totality of medical literature relevant to Zofran and its mechanism of action establish an increased risk of birth defects in babies exposed to Zofran during pregnancy.

82. GSK has at all relevant times failed to take any steps to disclose its knowledge and information concerning the risks of birth defects arising from Zofran use during pregnancy. GSK failed to act in this regard despite its knowledge that it had affirmatively marketed Zofran as safe and effective for treating pregnancy related nausea and vomiting.

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

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

84. 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 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 United States 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.

85. 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 Commonwealth and Florida, among others, as a safe treatment alternative for morning sickness in pregnant women.

86. 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.

87. 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.)

88. 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.

89. 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**."

90. GSK blatantly disregarded this mandate by the FDA. For example, in 2002, GSK's marketing materials to Ob/Gyn practitioners, GSK failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran treatment during pregnancy.

91. When the FDA first approved Zofran 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.

92. 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 Division 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.

93. GSK's primary purpose in undertaking this co-marketing arrangement was to promote Zofran to obstetricians and gynecologists during GSK's Consumer Healthcare Division sales force 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.

94. 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 she or 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.

95. 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.

96. 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).

97. 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.

98. GSK's 2012 civil settlement with the United States covered improper promotional conduct that was part of an overarching plan to maximize highly profitable Zofran sales without due regard to laws designed to protect patient health and safety. Another component of that plan led to a separate $150 million settlement between GSK and the United States in 2005. In or around 1993, a GSK marketing document sent to all of its sales and marketing personnel nationwide advised that they should emphasize to medical providers not only the benefits of Zofran but also the financial benefits to the providers by prescribing Zofran. Specifically, "[b]y using a 32 mg bag [of Zofran], the physician provides the most effective dose to the patient and increases his or her profit by $___ in reimbursement." GSK's marketing focus on profits to the prescribers misleadingly aimed to shift prescribers' focus from the best interests of patients to personal profit. In this regard, GSK marketed Zofran beginning in the 1990s as "convenient" and offering "better reimbursement" to prescribers. GSK detailed this plan in a marketing document for its Zofran premixed IV bag entitled "Profit Maximization – It's in the Bag." Upon information

and belief, GSK's conduct described above continued until the DOJ began investigating it in the early 2000s.

Plaintiff's Exposure to Zofran

99. Plaintiffs Janet Seper and Charles Beckenstein are the natural guardians and parents of minor child Z.B.

100. To alleviate and prevent the symptoms of morning sickness, Plaintiff Janet Seper took Zofran during her entire pregnancy with Z.B.

101. Z.B. was born in 2004.

102. Z.B. was born with a VSD as a direct and proximate result of her prenatal exposures to Zofran.

103. Z.B. has undergone corrective surgery for her VSD. Her birth defects put her at risk of future corrective surgery and impair her ability to develop fully and enjoy her childhood and life thereafter.

104. Plaintiff Janet Seper took Zofran during her pregnancy, including her first trimester of pregnancy, thereby exposing her unborn child, Z.B., to Zofran *in utero* during the critical period when tissues are susceptible to developmental insult from environmental exposure. This exposure resulted in Z.B.'s VSD birth defect.

105. Z.B. has no family history of any of the conditions from which she suffers.

106. Plaintiff Janet Seper was unaware of the dangerousness of Zofran or the fraudulent nature of GSK's marketing of Zofran when took Zofran during pregnancy.

107. Had Plaintiff Janet Seper and her prescribers known of the increased risk of birth defects associated with Zofran, and had they not been misled by GSK's promotion of the drug's purported safety benefits for use in pregnancy (on which they reasonably relied), Plaintiff would not have taken Zofran during pregnancy and Z.B. would not have been born with congenital malformations.

108. As a direct and proximate result of GSK's conduct, Plaintiffs and their daughter Z.B. have suffered and incurred harm including severe 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.

109. Plaintiffs Janet Seper and Charles Beckenstein file this lawsuit within the applicable limitations period of first suspecting that GSK's wrongful conduct caused the appreciable harm sustained by their daughter, Z.B. 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.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

110. 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.

111. 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.

112. 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

117. Had Plaintiff Janet Seper not taken Zofran, her baby, Z.B., would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a truthful and non-misleading manner, Plaintiff Janet Seper would never have taken Zofran.

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

119. As a result of the foregoing acts and omissions, Z.B. requires and will require more health care and services and did incur medical, health, incidental and related expenses.

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

SECOND CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY)

121. 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.

122. GSK is a merchant with respect to goods of the kind Plaintiff Janet Seper received. GSK impliedly warranted that its product was merchantable. GSK impliedly warranted that its product was fit for the particular purpose of being used safely in the treatment of pregnancy-related nausea. Plaintiff Janet Seper and her health care providers relied on GSK's skill, judgment and superior access to the drug's risk profile when deciding to use GSK's product.

123. GSK's 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. GSK's product was dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including Plaintiff Janet Seper and her medical providers.

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

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

126. As a result of the foregoing acts and omissions, Z.B. requires and will require more health care and services and did incur medical, health, incidental and related expenses.

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

THIRD CAUSE OF ACTION
(STRICT LIABILITY)

128. 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.

129. Zofran was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by GSK.

130. Zofran was defective and unreasonably dangerous at the time it left GSK's control in that it failed to include adequate warnings, instructions and directions related to the dangerous risk of using Zofran to treat pregnancy-related nausea.

131. Zofran was also defective and unreasonably dangerous 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 of relieving pregnancy-related nausea and neither the safety nor the efficacy of Zofran had been established for that purpose.

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

133. Prescribing physicians, health care providers and mothers-to-be neither knew, nor had reason to know of the existence of the unreasonable risks of harm Zofran posed to pregnant women and their offspring. Ordinary consumers would not have recognized the potential risks or side effects of Zofran because GSK failed to include appropriate warnings and masked the risks through unbalanced off-label promotion of Zofran for use by pregnant women.

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

135. As a result of the foregoing acts and omissions, Z.B. was caused to suffer birth defects that are severe in nature, as well as physical pain and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications.

136. As a result of the foregoing acts and omissions, Z.B. requires and will require more health care and services and did incur medical, health, incidental and related expenses.

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

FOURTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

138. 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.

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

140. 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 Janet Seper and her providers.

141. 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 Janet Seper and her healthcare providers.

142. In violation 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.

143. In violation 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 Janet Seper 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; and

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

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

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

146. 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 Janet Seper and her providers, to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy-related nausea.

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

148. In reasonable reliance upon said representations, Plaintiff Janet Seper's prescribers were induced to prescribe Zofran to her and recommend the drug as safe for treating pregnancy-related nausea, and she 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 Janet Seper would not have used the product and her medical providers would not have administered it and recommended it as safe.

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

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

151. As a result of the foregoing acts and omissions, Z.B. was caused to suffer birth defects that are severe in nature, as well as physical pain and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications.

152. As a result of the foregoing acts and omissions, Z.B. requires and will require more health care and services and did incur medical, health, incidental and related expenses.

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

FIFTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

154. 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.

155. 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 Janet Seper and her healthcare providers. GSK had exclusive access to material information about the teratogenic risks of Zofran, and GSK knew that neither Plaintiff Janet Seper nor her medical providers could reasonably discover that information.

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

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

a. GSK was illegally paying and offering remuneration and promoting financial incentives to providers to encourage them to promote and prescribe Zofran;

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

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

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

e. the risks of birth defects associated with the consumption of Zofran by pregnant women were not adequately tested prior to GSK's marketing of Zofran;

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

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

h. GSK's internal data and information signaled an association between Zofran use during pregnancy with birth defects.

158. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran for pregnancy-related nausea misled physicians, hospitals and healthcare providers, and expectant mothers including Plaintiff Janet Seper and her providers into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

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

160. Plaintiff Janet Seper 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 Janet Seper would not have used the product and her providers would not have prescribed it and at a minimum would have communicated to Plaintiff the pregnancy risks and how to avoid them.

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

162. As a result of the foregoing acts and omissions, Z.B. requires and will require more health care and services and did incur medical, health, incidental and related expenses.

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

SIXTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

164. 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.

165. 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 Janet Seper and her healthcare providers.

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

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

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

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

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

168. Plaintiff Janet Seper and her healthcare providers reasonably relied upon GSK's expertise, skill, judgment, and knowledge and upon their express and/or implied warranties that their product was safe, efficacious, adequately tested, of merchantable quality and fit for use during pregnancy. In justifiable reliance upon these misrepresentations, Plaintiff Janet Seper and her healthcare providers were induced to prescribe and use GSK's product.

169. Had GSK not made express and implied false statements, or revealed all material information about Zofran, Plaintiff Janet Seper would not have used the product and her providers would not have prescribed it.

170. As a result of the foregoing acts and omissions, Z.B. requires and will require more health care and services and did incur medical, health, incidental and related expenses.

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

SEVENTH CAUSE OF ACTION
(LOSS OF CONSORTIUM/LOSS OF CHILD'S SERVICES)

172. 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.

173. Z.B. is a minor child who is dependent upon her parents, Plaintiffs Janet Seper and Charles Beckenstein.

174. As a direct and proximate result of Defendant's negligence and wrongful conduct, Plaintiffs have been deprived of the society, love, comfort, affection, companionship, solace, moral support, care and services, of their child, Z.B., and are entitled to recovery for these losses.

175. As a direct and proximate result of Defendant's negligence and wrongful conduct, Plaintiffs incurred medical expenses and other pecuniary loss while treating Z.B.'s injuries.

176. Plaintiffs seek all damages available against GSK on account of the loss of their daughter's consortium.

EIGHTH CAUSE OF ACTION
(PUNITIVE DAMAGES)

177. 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.

178. Plaintiffs are entitled to punitive damages because Defendant's actions were reckless and without regard for the public's safety and welfare. Defendant misled both the medical community and the public at large, including Plaintiffs, by making false representations about concealing pertinent information regarding Zofran. Defendant downplayed, understated and disregarded their knowledge of the serious and permanent risks associated with the use of Zofran, despite information demonstrating that the product was unreasonably dangerous to unborn children.

179. The conduct of Defendant in designing, testing, manufacturing, promoting, advertising, selling, marketing, and distributing Zofran, and in failing to warn Plaintiffs and other members of the public of the dangers inherent in the use of Zofran, which were known to Defendant, was attended by circumstances of malice, avarice, or willful and wanton conduct,

done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiffs.

180. At all times material hereto, Defendant had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of Zofran.

181. Defendant breached its duty and were wanton and reckless in their actions, misrepresentations, and omissions toward the public generally, and Plaintiffs specifically, in the following ways: Defendant continued to promote the safety of Zofran, while providing consumers and their health care providers no warnings or insufficient warnings about the risk of birth defects associated with it, even after Defendant knew of that risk.

182. Defendant's conduct was a conscious and deliberate disregard for the rights and safety of consumers, including Plaintiffs, or with such wanton and/or reckless disregard, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

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 all elements and types of compensatory damages recoverable under the law applicable to this case, including, but not limited to, damages for injury, disfigurement, loss of function, emotional distress, pain and suffering, mental anguish and all other recoverable damages for the injuries suffered by the minor plaintiff.

b) For past and future medical, incidental and hospital expenses;

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

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

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

Dated: February 2, 2016

KREINDLER & KREINDLER, LLP

s/Julie Ferraro
Julie Ferraro, BBO # 665364
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JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Janet Seper and Charles Beckenstein, et al.

DEFENDANTS
GlaxoSmithKline LLC

(b) County of Residence of First Listed Plaintiff Hillsborough
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant New Castle
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Anthony Tarricone and Julie Ferraro, Kreindler & Kreindler LLP, 855 Boylston Street, Boston, MA 02116, (617)-933-5923

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☐ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC section 1332 , 28 USC section 1391

Brief description of cause:
Zofran case invoving minor injuries

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*

JUDGE Saylor DOCKET NUMBER 15-2657 FDS

DATE 02/02/2016

SIGNATURE OF ATTORNEY OF RECORD Julie Ferraro

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. Title of case (name of first party on each side only) Seper & Beckenstein, et al. v. GSK

2. Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).

☐ I. 410, 441, 470, 535, 830*, 891, 893, 895, R.23, REGARDLESS OF NATURE OF SUIT.

☐ II. 110, 130, 140, 160, 190, 196, 230, 240, 290,320,362, 370, 371, 380, 430, 440, 442, 443, 445, 446, 448, 710, 720, 740, 790, 820*, 840*, 850, 870, 871.

☑ III. 120, 150, 151, 152, 153, 195, 210, 220, 245, 310, 315, 330, 340, 345, 350, 355, 360, 365, 367, 368, 375, 385, 400, 422, 423, 450, 460, 462, 463, 465, 480, 490, 510, 530, 540, 550, 555, 625, 690, 751, 791, 861-865, 890, 896, 899, 950.

*Also complete AO 120 or AO 121. for patent, trademark or copyright cases.

3. Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.

MDL 15-md-2657 FDS

4. Has a prior action between the same parties and based on the same claim ever been filed in this court?

YES ☐ NO ☑

5. Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)

YES ☐ NO ☑

If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?

YES ☐ NO ☑

6. Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?

YES ☐ NO ☑

7. Do all of the parties in this action, excluding governmental agencies of the United States and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).

YES ☐ NO ☑

A. If yes, in which division do all of the non-governmental parties reside?

Eastern Division ☐ Central Division ☐ Western Division ☐

B. If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?

Eastern Division ☐ Central Division ☐ Western Division ☐

8. If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)

YES ☐ NO ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Anthony Tarricone & Julie Ferraro, Kreindler & Kreindler LLP

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