UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

ASHLEY DAVIS and CHARLES JANKE III, as Parents and Natural Guardians of C.J., a Minor, Plaintiffs, v. GLAXOSMITHKLINE LLC, Defendant.	CIVIL ACTION NO: 1:16-cv-888

COMPLAINT AND JURY DEMAND

COME NOW the Plaintiffs, Charles Janke III ("Charles") and Ashley Davis ("Ashley"), as parents and natural guardians of their son, C.J., a minor, (collectively "Plaintiffs"), who by and through 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 C.J. 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:

INTRODUCTION

1. Zofran is a powerful drug developed by GSK to treat patients who were afflicted with the most severe nausea imaginable – that suffered as a result of chemotherapy or radiation treatments in cancer patients.

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

3. Although the only FDA approval for this drug was for seriously ill patients, GSK marketed Zofran "off label" 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 other anti-nausea prescription drugs available on the market – which are FDA-approved in the United States for treating morning sickness in pregnant women – GSK never conducted a single clinical trial establishing the safety and efficacy of Zofran for treating pregnant women before GSK marketed Zofran for the treatment of pregnant women. GSK, in fact, excluded pregnant women from its clinical trials used to support its application for FDA approval of Zofran. In short, GSK simply chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment during pregnancy. GSK avoided conducting these studies and buried any internal analyses of Zofran's teratogenic potential because they would have hampered its marketing of Zofran and decreased profits by linking the drug to serious birth defects. GSK's conduct was tantamount to using expectant mothers and their unborn children as human guinea pigs.

4. As a result of GSK's nationwide fraudulent marketing campaign, Zofran was placed into the hands of unsuspecting pregnant women and in the 2000s became the number one most prescribed drug for treating morning sickness in the United States. These women ingested the drug because they innocently believed that Zofran was an appropriate drug for use in their circumstances. When they ingested the drug, these pregnant women had no way of knowing that Zofran had never been studied in pregnant women, much less shown to be a safe and effective treatment for pregnancy-related nausea. Zofran would never have become the most prescribed

morning sickness drug in the United States, and Plaintiff would never have taken it, if GSK had not misleadingly marketed the drug as a safe and efficacious treatment for morning sickness.

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

6. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date, including reports of the same congenital anomalies suffered by Plaintiff. 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.

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

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

8. Around the same time, 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.

9. 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.)

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

11. Plaintiffs' minor child, C.J., was born on January 18, 2007 with cleft palate and cleft lip after his mother, Ashley, was prescribed and began taking Zofran beginning early in her first trimester of pregnancy to alleviate and prevent the symptoms of morning sickness. . Ashley continued her use of Zofran through approximately October 20, 2007.

12. As a direct and proximate result of his exposure in utero to Zofran, C.J. has experienced a delay in his physical, language, and psychological development and interference with speaking and dental development.

13. C.J. was exposed to Zofran *in utero* during the periods when each of the tissues involved in the injuries described above were forming and were susceptible to developmental insult from environmental exposure.

14. There is no known genetic cause for C.J.'s condition and C.J. has no immediate family history of any of the conditions from which he suffers.

15. Had Ashley known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, she would never have taken Zofran, and her child would not have been injured as described herein.

16. 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.

JURISDICTION AND VENUE

17. 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.

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

19. At all times herein mentioned, GSK conducted, and continues to conduct, a substantial amount of business activity and has committed a tort, in whole or in part, in this judicial district. GSK is registered to conduct business in this district, and was engaged in interstate commerce when it advertised, promoted, supplied, and sold pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical

practitioners, and the general public, deriving substantial revenue in this district. GSK's plan to misleadingly market Zofran for pregnancy was executed nationwide, including in this district and State.

20. Recently the judicial panel on multidistrict litigation formed an MDL for cases against GSK involving its drug, Zofran, and resulting birth defects. The MDL is currently pending before the Honorable F. Dennis Saylor IV in the United States District Court for the District of Massachusetts with a caption of: *In re: Zofran (Ondansetron) Products Liability Litigation*, MDL No.: 1:15-md-2657-FDS. Plaintiffs do not oppose the transfer of this action to the MDL.

PARTIES

21. Plaintiff Ashley Davis is currently a resident and citizen of Greenfield, Hancock County, Indiana. Ashley is C.J.'s mother. During all times relevant to her pregnancy and delivery of C.J., Ashley was a resident and citizen of Indianapolis, Marion County, Indiana. She was prescribed and took Zofran in Indiana during her pregnancy with C.J.

22. Plaintiff Charles Janke III is currently a resident and citizen of Greenfield, Hancock County, Indiana. He is C.J.'s father. During all times relevant to Ashley's pregnancy and delivery of C.J., Charles was a resident and citizen of Indianapolis, Marion County, Indiana.

23. 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 with its principal place of business in Wilmington, Delaware.

24. 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.

25. At all relevant times, GSK conducted business in this State and has derived substantial revenue from products, including Zofran, sold in this State.

PERTINENT BACKGROUND ON ZOFRAN

26. 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.)

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

28. 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).

29. 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.

30. 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).

31. 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).

32. 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)

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

34. 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.

35. 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.

36. 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.

37. 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.

38. 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

39. 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.

40. 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.

41. 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).

42. 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.

43. 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.

44. 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.

45. 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."

46. 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

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

48. 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.

49. 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.

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

51. 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.

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

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

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

54. 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").

55. 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.

56. 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.

57. 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.

58. 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.

59. Additional studies have shown an increased risk for cleft palate associated with Zofran/ondansetron use within the first trimester of pregnancy. For example, a recent large

control study detected a more-than 2-fold increased risk for cleft palate associated with ondansetron taken in the first trimester of pregnancy. Anderka, et al., *Medications Used to Treat Nausea and Vomiting of Pregnancy and the Risk of Selected Birth Defects*, Wiley Periodicals, Inc. (2011); *see also* Koren, G., M.D., *Scary Science: Ondansetron Safety in Pregnancy—Two Opposing Results from the Same Danish Registry*, 36 TDM 1 (2014).

60. 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

61. 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).

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

63. 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.*

64. 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).

65. 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 Ashley Davis and her prescribing healthcare provider.

66. 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.

67. 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.

68. 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."

69. 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.

70. 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.

71. 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."

72. 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**."

73. 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.

74. GSK's inclusion of the phrase "Pregnancy Category B" in Zofran's prescribing information refers to the FDA's pregnancy categorization scheme applicable to prescription drugs in the United States. The FDA established five categories to indicate the potential of a drug to cause birth defects if used during pregnancy. The former system of pregnancy labeling consists of five letter-categories (A, B, C, D, and X, in order of increasing risk).

75. 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 failed to warn of the potential hazards to a fetus arising from Zofran use during pregnancy.

76. 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."

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

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

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

79. 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 State.

80. 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.

81. 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.

82. 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.)

83. 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.

84. 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**."

85. GSK disregarded this mandate by the FDA. For example, GSK's marketing materials as early as 2000 in widely circulated 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.

86. 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.

87. 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.

88. 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.

89. 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.

90. 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.

91. 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).

92. 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.

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

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

Plaintiffs' Exposure to Zofran

94. Plaintiff Ashley Davis is the mother and natural parent and guardian of C.J.

95. To alleviate and prevent symptoms of morning sickness, Ashley was prescribed Zofran beginning early in her first trimester of pregnancy with C.J. and she continued Zofran use through approximately October 2006.

96. C.J. was born on January 18, 2007 and diagnosed with cleft palate and cleft lip.

97. As a result of these birth defects, C.J. is unable to participate fully in life and has required multiple surgeries and ongoing speech therapy. C.J. also exhibits physical malformations resulting from the clefts and subsequent surgeries. Additionally, C.J. has experienced developmental delays, including interference with speaking and dental development.

98. C.J. was exposed to Zofran *in utero* during the periods when his facial tissues were forming and susceptible to developmental insult from environmental exposure.

99. There is no known genetic cause for C.J.'s condition. C.J. has no family history of any of the conditions from which he suffers.

100. Ashley and her direct medical providers were 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.

101. Had Ashley 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 C.J. would not have been born with birth defects and would not be experiencing related developmental delays and emotional problems.

102. As a direct and proximate result of GSK's conduct, Plaintiffs Ashley Davis, Charles Janke III, and their son, C.J., 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.

103. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that GSK's wrongful conduct caused the appreciable harm sustained by their son, C.J. 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
VIOLATION OF INDIANA'S PRODUCT LIABILITY ACT
IND. CODE § 34-20-1 *ET SEQ.*

104. 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.

105. GSK is a manufacturer, as defined by Ind. Code § 34-6-2-77, who, at all relevant times was in the business of and did design, research, develop, manufacture, test, inspect, package, label, promote, market, advertise, distribute, and sell Zofran to consumers.

106. GSK placed its product, Zofran, into the stream of commerce.

107. GSK expected Zofran to reach, and it did reach consumers, including Plaintiff, without substantial alteration in the condition in which it was sold.

108. Zofran was defective and unreasonably dangerous in that it was dangerous to an extent beyond which would be contemplated by reasonable persons among those considered to be expected users or consumers. Zofran was also in a condition that was unreasonably dangerous to expected users and consumers when consumed in a reasonably expectable way in light of GSK's marketing efforts—ingestion by pregnant women for the treatment of morning sickness.

109. 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. At the time the product left GSK's control, there existed an alternative design that was capable of preventing C.J.'s injuries. Moreover, the

likelihood that Zofran's design would cause damage and the severity and gravity of that damage outweighed the burden on GSK of adopting an alternative design. Finally, no warning was provided about the dangerousness of Zofran to pregnant women.

110. The foreseeable risks associated with the design or formulation of Zofran, include but are not limited to, the fact that Zofran can cause birth defects, and the fact that the design or formulation of Zofran is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or did not have the claimed benefits.

111. At all times herein mentioned, due to GSK's misleading off-label marketing of Zofran, the drug was prescribed and used as intended by GSK and in a manner reasonably foreseeable to GSK. GSK knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of GSK's conduct.

112. In light of the reasonably foreseeable risks of congenital birth defects, associated with the use of Zofran, the advertised benefits of Zofran are inadequate and insufficient because Zofran does not confer additional benefits to the consumer that are not conferred by other forms of anti-nausea medications, which do not present the same risk of congenital birth defects associated with Zofran.

113. The harm for which Plaintiffs seek to recover compensatory damages was not caused by any inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community. The characteristics of the product that caused the harm could easily be eliminated by simply including warnings regarding the risk of birth defects, particularly when used during the

first trimester of pregnancy. None of these characteristics exist in other forms of anti-nausea medication, which confer the same benefits to the consumer without the risk of injury. At the time the Zofran left the control of its manufacturer, a practical and technically feasible alternative design or formulation was available that would have prevented the harm for which the Plaintiffs seek to recover compensatory damages without substantially impairing the usefulness or intended purpose of the product.

114. 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.

115. GSK failed to exercise reasonable 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.

116. GSK, its agents, servants, and/or employees, failed to exercise reasonable care, failed to comply with existing standards of care, and are strictly liable for 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. Failing to evaluate available data and safety information concerning Zofran use in pregnant women;

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

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

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

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

g. 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;

h. 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;

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

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

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

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

m. Failing to advise Plaintiff Ashley Davis, 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;

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

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

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

118. In fact, GSK expressly represented to consumers and the medical community that Zofran was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

119. As a result, prescribing physicians, health care providers, and mothers-to-be, including Plaintiff Ashley Davis and her health care providers, neither knew, nor had reason to know at the time of their use of Zofran of the existence of the aforementioned defects. Ordinary consumers would not have recognized the potential risks or side effects for which GSK failed to include appropriate warnings, and which GSK masked through unbalanced promotion of Zofran specifically for treatment of pregnant women.

120. Zofran does not conform to GSK's express representations because it is not safe, has numerous and serious side effects and causes severe and permanent injuries.

121. At the time of the making of the express warranties, GSK knew or should have known of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. Zofran was unreasonably dangerous because it failed to conform to an express warranty of GSK.

122. At the time of the making of the express warranties, GSK knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

123. GSK also impliedly represented and warranted to the users of Zofran and their physicians, healthcare providers, and/or the FDA that Zofran was safe and of merchantable quality and fit for the ordinary purpose for which GSK intended such product to be used.

124. At all relevant times, GSK knew of the uses for which it intended Zofran to be used and impliedly warranted the product to be of merchantable quality and safe and fit for such uses.

125. GSK was aware that consumers, including Plaintiff Ashley Davis, would use Zofran in the manner intended by GSK.

126. Plaintiffs and the medical community reasonably relied upon the judgment and sensibility of GSK to market and sell Zofran only if it was indeed of merchantable quality and safe and fit for its intended use.

127. Plaintiffs, other consumers, and members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of GSK for use of Zofran in recommending, prescribing, and/or dispensing Zofran.

128. At all relevant times Zofran did not perform as safely as an ordinary consumer and the medical community would expect, when used as intended or in a reasonably foreseeable manner.

129. GSK herein breached the aforesaid duties and warranties, as its drug Zofran was defective and was not of merchantable quality or safe and fit for its intended use.

130. GSK knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Zofran was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not identified as risks by GSK.

131. Plaintiffs were in the class of persons that GSK should reasonably foresee as being subject to the harm caused by the defective condition of Zofran.

132. GSK knew or should have known that the children of consumers such as Plaintiff Ashley Davis would foreseeably suffer injury as a result of GSK's failure to exercise reasonable care, as set forth above.

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

134. Had GSK marketed Zofran in a truthful and non-misleading manner, Plaintiff Ashley Davis would never have taken Zofran.

135. Had Plaintiff Ashley Davis not taken Zofran, Plaintiff C.J. would not have suffered those injuries and damages as described herein with particularity.

136. As a result of the foregoing acts and omissions, Plaintiff C.J. suffered 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.

137. As a result of the foregoing acts and omissions, C.J. has required and will require health care and services and medical, health, incidental, and related expenses.

138. Plaintiffs Ashley Davis, Charles Janke III and their son, C.J., have also sustained severe emotional distress and suffering as a result GSK's wrongful conduct which caused the injuries to C.J.

139. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was malicious, willful, wanton, oppressive, fraudulent, reckless, and, at the very least grossly negligent in that it manifested a knowing and reckless indifference toward, and a disregard of, the rights and safety of others.

SECOND CAUSE OF ACTION
FRAUD

140. 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.

141. GSK, from the time it first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Zofran, and up to the present, willfully deceived Plaintiff by concealing from her, her physicians and the general public, the true facts concerning Zofran, which GSK had a duty to disclose.

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

143. 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 Ashley Davis and her providers.

144. 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 Ashley Davis and her healthcare providers.

145. 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.

146. 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 Ashley Davis and her providers, that:

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

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

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

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

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

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

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. 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 Ashley Davis and her providers, in order to induce them to recommend, prescribe, dispense, and/or purchase Zofran to treat pregnancy-related nausea.

152. At the time these representations were made by GSK and, at the time Plaintiff Ashley Davis used Zofran, Plaintiff Ashley Davis and her healthcare providers were unaware of the falsity of said representations and reasonably believed them to be true.

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

154. As a result of the foregoing acts and omissions, C.J. suffered 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.

155. Plaintiffs have also suffered severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their son, C.J.

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

157. GSK's conduct was malicious, willful, wanton, oppressive, fraudulent, reckless, and, at the very least grossly negligent in that it manifested a knowing and reckless indifference toward, and a disregard of, the rights and safety of others.

158. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. Plaintiff incorporates by reference each of the allegations set forth in this Complaint as though fully set forth herein.

THIRD CAUSE OF ACTION
VIOLATION OF INDIANA'S CONSUMER SALES ACT
IND. CODE § 24-5-0.5-1, *ET SEQ.*

159. 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.

160. GSK's sale, marketing, promotion, and distribution of Zofran under the guise that it was a safe and effective product were unfair and/or deceptive acts or practices.

161. GSK represented that its product was of a particular standard and quality because of its safety and effectiveness. Because Zofran is in fact not safe and/or effective, GSK's representations violate Ind. Code § 24-5-0.5-3(2).

162. GSK knew, or should have known that Zofran was not safe or effective and had side effects, which included the increased risk of birth defects.

163. Consumers, including Plaintiff, purchased and used Zofran based on representations made by GSK that Zofran was safe and effective.

164. By making false and misleading representations and omissions, GSK intended that Plaintiffs would rely on its false statements and material omissions and intended to induce Plaintiffs to purchase and use Zofran.

165. Plaintiffs were induced to purchase and use Zofran by relying on the statements and representations made by GSK that were false, misleading, and deceptive because Zofran is not safe and effective to use.

166. The unfair, false, misleading, and deceptive practices of GSK caused C.J. to incur severe and permanent physical and emotional injuries, including but not limited to cleft palate and cleft lip. Plaintiffs have endured and will continue to endure pain, suffering, and loss of enjoyment of life, and have suffered and will continue to suffer economic loss, incurring significant expenses for medical care and treatment.

167. Because GSK intentionally, knowingly, and willfully, misrepresented that their product was of a particular standard and quality, Plaintiff is entitled to recover additional damages as provided by Ind. Code § 24-5-0.5-4(a).

168. If Plaintiff prevails in this action, he is entitled to attorneys' fees from GSK as provided by Ind. Code § 24-5-0.5-4(a).

PUNITIVE DAMAGES ALLEGATIONS

169. 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.

170. Prior to the manufacturing, sale, and distribution of Zofran, GSK knew that Zofran was in a defective condition as previously described herein and knew that those who were prescribed the medication and their minor children would experience and did experience severe physical, mental, and emotional injuries. Further, GSK, through its officers, directors, managers, and agents, knew that Zofran presented a substantial and unreasonable risk of harm to the public, including Plaintiffs and as such, GSK unreasonably subjected consumers of said drugs to risk of injury or death from using Zofran.

171. Despite its knowledge, GSK, acting through its officers, directors and managing agents for the purpose of enhancing GSK's profits, knowingly and deliberately failed to remedy the known defects in Zofran and failed to warn the public, including Plaintiffs, of the extreme risk of injury occasioned by said defects inherent in Zofran. GSK and its agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Zofran knowing these actions would expose persons to serious danger in order to advance GSK's pecuniary interest and monetary profits.

172. The acts, conduct, and omissions of GSK, as alleged throughout this Complaint were malicious, willful, wanton, oppressive, fraudulent, reckless, and, at the very least grossly negligent in that it manifested a knowing and reckless indifference toward, and a disregard of, the rights and safety of others.

173. GSK committed these acts with flagrant disregard of the safety of persons, including Plaintiffs, who might be harmed by Zofran. GSK's outrageous and unconscionable

conduct warrants an award of exemplary and punitive damages against GSK in an amount appropriate to punish and make an example of GSK.

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 punitive and/or exemplary damages;

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

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

Respectfully submitted,

COHEN & MALAD, LLP

Dated: April 20, 2016

/s/ Edward B. Mulligan V
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Counsel for Plaintiffs

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

Ashley Davis and Charles Janke III, as Parents and Natural Guardians of C.J., a Minor

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jeff S. Gibson
Cohen & Malad, LLP
One Indiana Square, Suite 1400
Indianapolis, IN 46204 317-636-6481

DEFENDANTS

GlaxoSmithKline LLC

County of Residence of First Listed Defendant New Castle, DE
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

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 U.S.C. 1332

Brief description of cause:
Defective Pharmaceutical Drug

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,001.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE F. Dennis Saylor DOCKET NUMBER 1:15-md-2657-FDS

DATE 04/20/2016

SIGNATURE OF ATTORNEY OF RECORD /s/ Jeff S. Gibson

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____