UNITED STATES DISTRICT COURT OF THE EASTERN DISTRICT OF LOUISIANA

Jody Huffmaster, Individually and as Parent and Natural Guardian of B.H., a Minor,	*	
	*	CIVIL ACTION NO:
Plaintiff,	*	
	*	COMPLAINT
v.	*	
	*	JURY DEMANDED
GlaxoSmithKline LLC,	*	
	*	
Defendant.	*	
	*	

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff, Jody Huffmaster, individually and on behalf of her son, B.H., a minor, ("Plaintiff"), who by and through the undersigned counsel hereby submit this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "Defendant) for compensatory damages, equitable relief, and such other relief deemed just and proper arising from injuries to B.H. as a result of his prenatal exposure to the prescription drug Zofran®, also known as ondansetron. In support of this Complaint, Plaintiff alleges the following:

PRELIMINARY STATEMENT

1. GSK developed Zofran® to treat and prevent severe nausea and vomiting resulting from chemotherapy and/or radiation given to cancer patient.

2. In 1991, the Food and Drug Administration ("FDA") approved the use of Zofran only to treat cancer patients who were undergoing chemotherapy and radiation therapy for extreme nausea and vomiting resulting from these therapies.

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

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 circumstance. When they ingested the drug, these pregnant women had no way of knowing that Zofran had never been studied in pregnant women, much less shown to be a safe and effective treatment for pregnancy-related nausea. Zofran would never have become the most prescribed

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

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 B.H. 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 Plaintiff herein.

11. Plaintiff's minor child, B.H., was born in 2007 with numerous congenital defects, including cleft palate, clubfeet, and respiratory distress syndrome and apnea, after his mother, Plaintiff Jody Huffmaster, was prescribed and began taking Zofran beginning early in her first trimester of pregnancy and took it continuously from then through her third trimester to alleviate and prevent the symptoms of morning sickness. B.H. has required two surgeries in his short life to address the defects caused by Zofran.

12. B.H. 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.

13. There is no known genetic cause for B.H.'s condition. B.H. has no family history of any of the conditions from which he suffers. In addition, B.H. has two siblings who were born healthy and vibrant after Ms. Huffmaster carried them for full-term pregnancies.

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

15. Plaintiff brings 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

16. 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 Plaintiff is a Citizen.

17. Venue is proper in this district pursuant to 28 U.S.C. § 1331 inasmuch as a substantial part of the events or omissions giving rise to the claims occurred in this district.

18. At all relevant times herein, GSK has conducted a substantial amount of business activity in this district. GSK is registered to do conduct business in this district, engaged in interstate commerce in this district and derived substantial revenue in this district when it advertised, promoted, supplied and sold Zofran and other pharmaceuticals to distributors and

retailers for resale to hospitals, clinics, physicians, other medical practitioners, and the general public. GSK's misleading campaign for marketing Zofran to pregnant women, although devised outside of this district, was executed nationwide, including in this district.

PARTIES

19. Plaintiff, Jody Huffmaster, is a citizen of the United States. She is the mother and natural guardian of B.H., who lives with her. Plaintiff resides in Cabot, Arkansas.

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

21. 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.

22. At all relevant times, GSK conducted business in this district and State and has derived substantial revenue from the sale of pharmaceuticals, including Zofran, sold in this district and State.

FACTUAL BACKGROUND

23. 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)

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

25. The active ingredient in Zofran is ondansetron hydrochloride which is an anti-emetic selective serotonin receptor antagonist of the 5-hydroxytryptamine receptor type 3 ($5HT_3$) receptor type.

26. While its mechanism of action has not been fully characterized, ondansetron is not a dopamine-receptor antagonist. Serotonin receptors of the $5\text{-}HT_3$ type are present both peripherally on vagal nerve terminals in the gastrointestinal tract and centrally in the chemoreceptor trigger zone of the area postrema of the central nervous system.

27. Zofran is believed to block the action of serotonin at the $5HT_3$ receptors located along vagal nerve terminals and at the chemoreceptors located in the area postrema (the area of

the brain that controls the vomit reflex). In other words, Zofran inhibits, blocks or antagonizes the serotonin activity in the areas of the body that trigger nausea and vomiting.

28. Zofran was the first $5HT_3$ receptor antagonist approved by the FDA for marketing in the United States. Other $5HT_3$ receptor antagonist include Kytril® (granisetron) (FDA-approved 1994), Anzemet® (dolasetron) (FDA-approved 1997), and Aloxi® (palonosetron) (FDA-approved 2003).

29. Zofran is available in several formulations: injection (2 mg/mL), premixed injection (32 mg/50ml and 4 mg/50 ml), oral tablets (4 mg, 8 mg and 24 mg); orally disintegrating tablets (4 mg and 8 mg) and an oral solution (4 mg/5 mL).

30. GSK has obtained FDA approval for the following formulations 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)

31. GSK has obtained FDA approval for the following uses:

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.

32. The FDA has never approved Zofran for the prevention of nausea and vomiting associated with morning sickness or any other condition or complication associated with pregnancy.

33. To lawfully market any pharmaceutical for the prevention or treatment of specific condition or disease, including Zofran, the FDA must first approve the drug for its intended purpose after reviewing evidence demonstrating that the drug is safe and effective (including appropriate and sufficient clinical trials).

34. 32. 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 a specific treatment or prevention of a disease or condition, a pharmaceutical company may not legally market its drug for that purpose.

35. GSK has never applied to the FDA for approval to market Zofran for the prevention of nausea and vomiting associated with morning sickness in pregnant women.

36. GSK has not submitted any data to the FDA demonstrating that Zofran is safe or effective for prevention of nausea and vomiting associated with morning sickness in pregnant women.

37. GSK has not performed any clinical studies of Zofran for the prevention of nausea and vomiting associated with morning sickness in pregnant women.

38. GSK, however, possessed the financial and scientific resources to perform the appropriate clinical studies to develop the data to demonstrate the safety and efficacy of Zofran

for the prevention of nausea and vomiting associated with morning sickness in pregnant women so that GSK could lawfully apply to the FDA for approval of Zofran for such use.

39. Instead, GSK has illegally circumvented the FDA-approval process by marketing Zofran for the prevention of nausea and vomiting associated with 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 "off-label" promotion, constitutes fraudulent marketing.

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

THE SCIENTIC FACTS

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 administered Zofran through intravenous (I.V.) administration at doses of 0, 0.5, 1.5, and 4mg/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.

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 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.

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 30mg/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 5.5mg/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. And yet that is precisely what GSK did.

Early Reports to GSK of Zofran-Related Birth Defects

49. 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).

50. 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.

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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."

54. Even assuming that these animal studies do not conclusively reveal evidence of potential harm to a fetus exposed to Zofran, GSK was aware that animal studies are not necessarily predictive of human response. For example, a drug formerly prescribed to alleviate morning sickness, thalidomide, is an infamous teratogenic in humans, but animal studies involving the drug failed to demonstrate such an increased risk of birth defects in animals. GSK conducted studies of thalidomide and its toxicity before GSK developed Zofran and before it marketed Zofran for the treatment of morning sickness in pregnant women. Moreover, since at least 1993, GSK has stated in its prescribing information for Zofran that "animal reproduction studies are not always predictive of human response." Therefore, GSK has been aware since at least when it began marketing and selling Zofran that GSK could not responsibly rely on its animal studies as a basis for promoting Zofran use in pregnant women. GSK nevertheless went forward with marketing and promoting Zofran to pregnant women.

55. By 2000, GSK had received at least 32 reports of birth defects arising from Zofran treatment in pregnant women. These reports included congenital heart disease, dysmorphism, intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomaly, congenital musculoskeletal anomalies, and orofacial anomalies, among others.

56. In many instances, GSK received multiple reports in the same month, the same week and even the same day. For example, on or about September 13, 2000, GSK received three separate reports involving Zofran use and adverse events. For two of those incidents, the impact on the baby was so severe that the baby died.

57. From 1992 to the present, GSK has received more than 200 reports of birth defects

in children who were exposed to Zofran during pregnancy.

58. 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 (including cleft palate), intrauterine death, stillbirth and severe malformations in newborns were frequently reported.

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

Epidemiology Studies And The Risk of Congenital Heart Defects

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

61. 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").

62. 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.

63. **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.

64. **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.

65. **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.

66. 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

67. 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).

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

69. 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.

70. 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).

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

72. 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.

73. 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.

74. 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."

75. 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.

76. 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.

77. 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."

78. By contrast, the Product Monograph for Zofran in Canada states "the safety of ondansetron for use in human pregnancy has not been established," and that "the use of ondansetron in pregnancy is not recommended."

79. 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.

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

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

> **Pregnancy Category D. If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans,** but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is

> needed in a life threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: "Pregnancy Category D. See "Warnings and Precautions" section. Under the "Warnings and Precautions" section, **the labeling must state: "[drug] can cause fetal harm when administered to a pregnant woman. . . . If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."**
>
> 21 C.F.R. § 201.57(f)(6)(i)(d) (emphasis added).
>
> **Pregnancy Category X. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both,** and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: "Pregnancy Category X. See `Contraindications' section." Under "Contraindications," **the labeling must state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman. . . . (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."**
>
> Id. § 201.57(f)(6)(i)(e) (emphasis added).

82. Beginning at least in 1992, GSK had positive evidence of human fetal risk posed by Zofran based more than 200 reports to GSK of birth defects, as well as epidemiology studies, and placental-transfer studies reporting on Zofran's teratogenic risk. GSK has never updated Zofran's labeling to disclose that Zofran can cause fetal harm when administered to a pregnant woman, and GSK has failed to warn of the potential hazards to a fetus arising from Zofran use during pregnancy.

83. 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."

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

85. Plaintiff hereby demands that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiff and similarly situated mothers and mothers-to-be, as GSK's wrongful conduct alleged herein is continuing. Plaintiff further demands that GSK fully and fairly comply, no later than June 2015, to remove the Pregnancy Category B designation from its drug product labeling for Zofran and fully and accurately summarize the risks of using Zofran during pregnancy, fully and accurately describe the data supporting that summary, and fully and accurately describe the relevant information to help health care providers make informed prescribing decisions and counsel women about the risks associated with use of Zofran during pregnancy.

GSK's Fraudulent, Off-Label Promotion of Zofran

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

87. 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.

88. 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.

89. 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.

90. 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.)

91. 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.

92. 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."

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

94. 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.

95. 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.

96. 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.

97. 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.

98. 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.

99. 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).

100. 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.

101. 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.

FACTS SPECIFIC TO PLAINTIFF

102. Plaintiff Jody Huffmaster is the mother and natural guardian of B.H.

103. To alleviate and prevent the symptoms of morning sickness, Plaintiff Huffmaster was prescribed Zofran beginning early in her first trimester of pregnancy with B.H., and she continued Zofran use through her third trimester.

104. B.H. was born in 2007.

105. At his birth, B.H. was diagnosed with several severe congenital defects, including cleft palate, and bilateral clubfeet, a direct and proximate result of his prenatal exposures to Zofran. B.H. has required at least two surgeries to correct the defects resulting from the injuries caused by Zofran.

106. B.H. was exposed to Zofran in utero during the periods when his cardiac tissues were forming and susceptible to developmental insult from environmental exposure.

107. There is no known genetic cause for B.H.'s condition. B.H. has no family history of any of the conditions from which she suffers. In addition, B.H. has two siblings who were born healthy and vibrant after Ms. Huffmaster carried them for full-term pregnancies.

108. Plaintiff Jody Huffmaster 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.

109. Had Plaintiff Jody Huffmaster 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 B.H. would not have been born with congenital malformations.

110. As a direct and proximate result of GSK's conduct, Plaintiff Jody Huffmaster and her son, B.H., 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.

111. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that GSK's wrongful conduct caused the appreciable harm sustained by her son, B.H. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful conduct that caused the injuries at an earlier time. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, the tortious nature of the conduct causing the injuries, until a short time before filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because GSK has misrepresented to the public and to the medical profession that Zofran is safe for use in pregnancy, and GSK has fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action. In all events, the statute of limitations is tolled for claims arising from injuries to minors.

FIRST CAUSE OF ACTION
STRICT LIABILITY (Ark. Code Ann. § 4-86-102)

112. Plaintiff realleges and incorporates by reference all paragraphs as though fully set forth herein.

113. Zofran was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by GSK in a defective condition at the time it left GSK's control in that, and not by way of limitation, the drug failed to include adequate warnings, instructions and directions relating to the dangerous risks birth defects

associated with the use of Zofran to treat pregnancy-related nausea rendering it unreasonably dangerous.

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

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

116. Had Plaintiff Jody Huffmaster not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a truthful and non-misleading manner, Ms. Huffmaster would never have taken Zofran.

117. Plaintiff Huffmaster also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

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

SECOND CAUSE OF ACTION
DECEPTIVE AND UNCONSCIONABLE TRADE PRACTIVES
UNDER THE ARKANSAS DECEPTIVE TRADE PRACTIVES ACT
("ADTPA" Ark. Code Ann. § 4-88-101 *et seq.*)

119. Plaintiff realleges and incorporates by reference all paragraphs as though fully set forth herein.

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

time it left GSK's control in that, and not by way of limitation, the drug failed to include adequate warnings, instructions and directions relating to the dangerous risks associated with the use of Zofran to treat pregnancy-related nausea. Zofran also was defective in its design because the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design. Safe and effective products were available for the purpose for which GSK marketed Zofran in pregnant women, and neither the safety nor the efficacy of Zofran for that purpose had been established.

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

122. Prescribing physicians, health care providers and mothers-to-be, including Plaintiff Huffmaster 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.

123. At all times herein mentioned, due to GSK's off-label marketing of Zofran, the drug was prescribed and used as intended by GSK and in a manner reasonably foreseeable to GSK. GSK knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care, as set forth above.

124. GSK, its agents, servants, and/or employees, made false representations regarding the safety and efficacy of Zofran for the treatment and prevention of nausea and vomiting in

pregnant woman associated with morning sickness in violation of the ADTPA, Ark. Code Ann. § 4-88-101 *et seq.* through 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.

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

126. Had Plaintiff Jody Huffmaster not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a truthful and non-misleading manner, Ms. Huffmaster would never have taken Zofran.

127. Plaintiff Huffmaster also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

128. As a result of the foregoing acts and omissions, Plaintiff requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Huffmaster is informed.

129. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others.

130. Plaintiff is also entitled to an award of punitive damages given that GSK's conduct was malicious, wanton, willful, oppressive, or exhibited a reckless indifference to the rights of others.

THIRD CAUSE OF ACTION
DESIGN DEFECT UNDER Ark. Code Ann. § 16-116-101 *et seq.*
(PRODUCTS LIABILITY)

131. Plaintiff realleges and incorporates by reference all paragraphs as though fully set forth herein.

132. Zofran was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by GSK and was defective at the time it left GSK's control in that, and not by way of limitation, the drug failed to include adequate warnings, instructions and directions relating to the dangerous risks associated with the use of Zofran to treat pregnancy-related nausea. Zofran also was defective in its design because the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design. Safe and effective products were available for the purpose for which GSK marketed Zofran in pregnant women, and neither the safety nor the efficacy of Zofran for that purpose had been established.

133. Prescribing physicians, health care providers and mothers-to-be, including Plaintiff Huffmaster 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.

134. At all times herein mentioned, due to GSK's off-label marketing of Zofran, the drug was prescribed and used as intended by GSK and in a manner reasonably foreseeable to GSK. GSK knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care, as set forth above.

135. GSK's conduct constitutes a violation of the Louisiana Product Liability Act, LSA-R.S. 9:2800.56 for selling a product with a design defect that renders it unreasonably dangerous. At the time the product left GSK's control, there existed an alternative design that was capable of preventing B.H.'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.

136. GSK, its agents, servants, and/or employees, failed to provide adequate warnings in violation of the Arkansas Product Liability Act, Ark. Code Ann. § 16-116-101 *et seq*. 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.

137. As a direct and proximate result of the defective nature of Zofran, B.H. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental

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

138. Had Plaintiff Jody Huffmaster not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a truthful and non-misleading manner, Ms. Huffmaster would never have taken Zofran.

139. Plaintiff Huffmaster also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

140. As a result of the foregoing acts and omissions, Plaintiff requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Huffmaster is informed.

141. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others.

142. Plaintiff is also entitled to an award of punitive damages given that GSK's conduct was malicious, wanton, willful, oppressive, or exhibited a reckless indifference to the rights of others.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
UNDER Ark. Code Ann. § 4-2-313 *et seq.*
(PRODUCTS LIABILITY)

143. Plaintiff realleges and incorporates by reference all paragraphs as though fully set forth herein.

144. At all times herein mentioned, GSK manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Zofran and/or have recently acquired GSK who have manufactured, compounded, portrayed, distributed,

recommended, merchandized, advertised, promoted and sold Zofran, to treat nausea in pregnant women.

145. 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.

146. 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.

147. 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 as provided by Ark. Code Ann. § 4-2-313 *et seq*.

148. 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.

149. 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.

150. Plaintiff, other consumers, and the medical community relied upon GSK's express warranties.

151. 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.

152. GSK herein breached the aforesaid express warranties, as its drug Zofran was defective.

153. GSK expressly represented to Plaintiff's physicians, healthcare providers, and the FDA that Zofran was safe and fit for use for the purposes warranted.

154. 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.

155. As a result of the foregoing breaches, B.H. was caused to suffer serious and dangerous side effects including personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

156. As a result of the foregoing breaches, Plaintiff and B.H. have suffered and incurred damages, including medical expenses and other economic and non-economic damages.

157. By reason of the foregoing, Plaintiff and B.H. have suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS UNDER Ark. Code Ann. § 4-2-314 & §4-2-315 ET SEQ.

158. Plaintiff realleges and incorporates by reference all paragraphs as though fully set forth herein.

159. GSK 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.

160. 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.

161. GSK was aware that consumers, including Ms. Huffmaster, would use Zofran in the manner intended by GSK.

162. Plaintiff 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.

163. GSK breached the implied warranty to consumers, including Plaintiff, as Zofran was not of merchantable quality or safe and fit for its intended use.

164. Consumers, including Plaintiff and the medical community, reasonably relied upon GSK's implied warranty for Zofran.

165. Zofran reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by GSK.

166. Said representations and warranties were false, misleading, and inaccurate in that Zofran was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

167. Ms. Huffmaster and her physicians and healthcare professionals reasonably relied upon the skill and judgment of GSK as to whether Zofran was of merchantable quality and safe and fit for its intended use.

168. Zofran was placed into the stream of commerce by GSK in a defective, unsafe, and inherently dangerous condition and it was expected to and did reach users, handlers, and persons coming into contact with product without substantial change in the condition in which it was sold.

169. GSK breached the aforesaid implied warranties, as its drug Zofran was not fit for its intended purpose and use.

170. As a result of the foregoing acts and omissions, B.H. was caused to suffer serious and dangerous side effects including but not limited to, severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

171. As a result of the foregoing acts and omissions, Plaintiff and B.H. have suffered and incurred damages, including medical expenses and other economic and non-economic damages.

SIXTH CAUSE OF ACTION
VIOLATION OF THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW
(73 P.S. § 201-1, *et seq.*)

172. Plaintiff realleges and incorporates by reference all paragraphs as though fully set forth herein.

173. Plaintiff purchased Zofran for personal, family or household purposes within the meaning of 73 P.S. § 201-9.2.

174. All of the acts complained of herein were perpetrated by GSK in the course of trade or commerce within the meaning of 73 P.S. § 201-2(3).

175. The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("Pennsylvania CPL") prohibits unfair or deceptive acts or practices, including: (i) "Representing that goods or services have … characteristics, … Benefits or qualities that they do not have;" (ii)

"Representing that goods or services are of a particular standard, quality or grade … if they are of another;:" (iii) "Advertising goods or services with intent not to sell them as advertised;" and (iv) "Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or misunderstanding." 73 P.S. § 201-2(4).

176. GSK engaged in unlawful trade practices, including representing that Zofran has characteristics, uses, benefits, and qualities which they do not have; representing that Zofran is of a particular standard and quality when it is not; advertising Zofran with the intent not to sell them as advertised; and engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

177. In the course of its business, GSK systematically devalued safety and marketed Zofran as a safe an effective for use in pregnant women as described herein and otherwise engaged in activities with a tendency or capacity to deceive. GSK also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of Zofran.

178. From as early as 1992, GSK knew of many serious side-effects of Zofran, because of the many clinical trials it had conducted as discussed above. GSK became aware of significant increased risk of birth defects associated with the use of Zofran by pregnant women, especially in the first trimester, years ago, but concealed all of that information until recently.

179. By failing to disclose and by actively concealing the significant increased risks of birth defects associated with the use of Zofran by pregnant women, by marketing Zofran as safe, reliable, and of high quality, and by presenting itself as a reputable manufacturer that valued safety, GSK engaged in unfair and deceptive business practices in violation of the Pennsylvania CPL.

180. In the course of GSK's business, it willfully failed to disclose and actively concealed the dangerous risk posed to pregnant women and their un-born children as discussed above.

181. GSK's unfair or deceptive acts or practices were likely to and did in fact deceive reasonable consumers, including Plaintiff, about the true safety and reliability of Zofran for the treatment and prevention of morning sickness in pregnant women.

182. GSK intentionally and knowingly misrepresented material facts regarding the Zofran with an intent to mislead Plaintiff.

183. GSK knew or should have known that its conduct violated the Pennsylvania CPL.

184. As alleged above, GSK made material statements about the safety and reliability of Zofran as a treatment for the prevention of nausea and vomiting in pregnant women associated with morning sickness that were either false or misleading.

185. GSK owed Plaintiff a duty to disclose the true safety and reliability of Zofran and the devaluing of safety at GSK, because GSK:

a. Possessed exclusive knowledge that it valued sales over safety and illegally marketed Zofran an off-label use for which it was not FDA approved and for which appropriate clinical trials had not been performed;

b. Intentionally concealed the foregoing from Plaintiff; and/or

c. Made incomplete representations about the safety and reliability of Zofran generally, and the dangerous risks to pregnant women, especially in the first trimester, of birth defects in particular, while purposefully withholding material facts from Plaintiff that contradicted these representations.

186. B.H. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications as a result of GSK's misrepresentations and its concealment of and failure to disclose material information.

187. GSK's violations present a continuing risk to Plaintiff as well as to the general public. GSK's unlawful acts and practices complained of herein affect the public interest.

188. Had Plaintiff Jody Huffmaster not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a truthful and non-misleading manner, Ms. Huffmaster would never have taken Zofran.

189. Plaintiff Huffmaster also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

190. As a direct and proximate result of GSK's violations of the Pennsylvania CPL, Plaintiff has suffered injury-in-fact and/or actual damage.

191. GSK is liable to Plaintiff for treble her actual damages or $100, whichever is greater, and attorneys' fees and costs. 73 P.S. § 201-9.2(a).

192. Plaintiff is also entitled to an award of punitive damages given that GSK's conduct was malicious, wanton, willful, oppressive, or exhibited a reckless indifference to the rights of others.

SEVENTH CAUSE OF ACTION
FRAUD BY CONCEALMENT

193. Plaintiff realleges and incorporates by reference all paragraphs as though fully set forth herein.

194. GSK concealed and suppressed material facts concerning the safety and efficacy of Zofran.

195. GSK concealed and suppressed material facts concerning the dangerous birth defects caused by Zofran when taken by pregnant women, especially in the first trimester, and that

it valued sales over safety and took steps to ensure that its employees did not reveal known safety defects to regulators or consumers.

196. GSK had a duty to disclose the many dangerous side effects of Zofran, especially for pregnant women during the first trimester because GSK knew the facts were not known to or reasonably discoverable by Plaintiff. GSK also had a duty to disclose because it made many general affirmative representations about the safety, efficacy, and lack of defects in Zofran, as set forth above, which were misleading, deceptive and incomplete without the disclosure of the additional facts set forth above regarding its actual safety record, safety philosophy, and practices and the actual safety and efficacy of Zofran. Under FDA rules and regulations, GSK had the duty to disclose not just the partial truth, but the entire truth. These omitted and concealed facts were material because they directly impacted Plaintiff's decision to take Zofran during pregnancy. Whether a manufacturer's products are safe and reliable, are material concerns to a consumer.

197. GSK actively concealed and/or suppressed these material facts, in whole or in part, to protect its profits and avoid negative press that would hurt the brand's image and cost GSK money, and it did so at the expense of Plaintiff.

198. Plaintiff was unaware of these omitted material facts and would not have acted as she did if she had known of the concealed and/or suppressed facts, in that she would not have taken Zofran while pregnant. Plaintiff's actions were justified given her lack of knowledge. GSK was in exclusive control of the material facts and such facts were not known to the public or Plaintiff.

199. Because of the concealment and/or suppression of the facts, B.H. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

200. Had Plaintiff Jody Huffmaster not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity. Had GSK marketed Zofran in a truthful and non-misleading manner, Ms. Huffmaster would never have taken Zofran.

201. Plaintiff Huffmaster also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

202. As a result of the foregoing acts and omissions, Plaintiff requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Huffmaster is informed.

203. Accordingly, GSK is liable to Plaintiff for damages in an amount to be proven at trial.

204. GSK's acts were done maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiff's rights and wellbeing to enrich GSK. GSK's conduct warrants an assessment of punitive damages in an amount sufficient to deter such conduct in the future, which amount is to be determined according to proof.

EIGHT CAUSE OF ACTION
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
(13 PA. CONS. STAT. ANN. § 2314)

205. Plaintiff realleges and incorporates by reference all paragraphs as though fully set forth herein.

206. GSK is s a merchant with respect to Zofran and other pharmaceuticals.

207. A warranty that Zofran was in merchantable condition was implied by law when GSK sold Zofran to Plaintiff.

208. Zofran, when sold and at all times thereafter, was not in merchantable condition and are not fit for the ordinary purpose for which it was intended. Specifically, Zofran is inherently

defective in that its use by pregnant women, especially in the first trimester, carries a significantly increased risk of birth defects.

209. GSK was provided notice of these issues by numerous complaints filed against it, by its own internal studies, and by numerous independent studies published before 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 2012.

210. As a direct and proximate result of GSK's breach of the warranties of merchantability, Plaintiff has been damaged in an amount to be proven at trial.

DEMAND FOR JURY TRIAL

Plaintiff demands 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, Plaintiff demands 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 damages in excess of the jurisdictional minimum of this Court;

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.

Dated: September 14, 2015

By:

/s/ James R. Dugan II

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