UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ALEXIS OSTRANDER, Individually and on behalf of her deceased daughter Baby Girl O. Plaintiff, Vs. GLAXOSMITHKLINE LLC Defendant.	)	Civil Action No. 16-cv-11536 MDL Docket No. 2657

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff, Alexis Ostrander, individually and on behalf of her deceased daughter Baby Girl O. ("Baby"), who by and through the undersigned counsel hereby submits this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "Defendant") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to and death of Baby as a result of her prenatal exposures to the prescription drug Zofran®, also known as ondansetron. In support of this Complaint, Plaintiff alleges the following.

INTRODUCTION

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

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

3. Although the only FDA approval for this drug was for seriously ill patients, GSK marketed Zofran "off label" as a safe and effective treatment for the common side effect of normal

pregnancy - pregnancy-related nausea and vomiting ("morning sickness"). GSK did this despite having knowledge that such representations were false, as GSK had not undertaken a single study on the effects of this powerful drug on a pregnant mother or her growing child *in utero.* Unlike another anti-nausea prescription drug available on the market, which is FDA- approved in the United States for treating morning sickness in pregnant women, GSK never conducted a clinical trial for morning sickness before marketing Zofran to pregnant women. GSK chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment of morning sickness. GSK avoided conducting these studies because they would have hampered its ability to market Zofran and thereby decreased profits by showing the drug was linked to serious birth defects. GSK's conduct effectively used using expectant mothers and their unborn children as human guinea pigs.

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

5. By contrast, GSK knew that Zofran was unsafe for ingestion by expectant mothers. In the 1980s, GSK conducted animal studies which revealed evidence of toxicity, intrauterine deaths and malformations in offspring, and further showed that Zofran's active ingredient transferred through the placental barrier of pregnant mammal s 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 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. GSK never disclosed these reports to pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological studies that have demonstrated an elevated risk of developing birth defects such as those suffered in this case. GSK has not disclosed this to pregnant women or their physicians. Instead, GSK sales representatives specifically marketed and promoted Zofran as a morning sickness drug throughout the relevant time periods discussed herein.

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.

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

9. GSK's written agreement with the United States reports GSK's settlement of claims that GSK:

a. "promoted the sale and use of Zofran for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including hyperemesis and pregnancy-related nausea)"

b. "made and/or disseminated unsubstantiated and false representations about the safety and efficacy of Zofran concerning the uses described in subsection (a) [hyperemesis and pregnancy-related nausea]"

c. "offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran"

(Settlement Agreement, p. 5, July 2, 2012.)

10. As the holder of the NDA for Zofran, GSK knew that pharmaceutical companies filing and holding abbreviated new drug applications ("ANDA") would rely on GSK's representations to the FDA, physicians and patients that Zofran was safe and effective. GSK also knew that any generic manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v). GSK further knew that pharmacies routinely substitute less expensive generic drugs such as ondansetron in place of branded drugs such as Zofran. In other words, GSK knew, or should have known, that as long as they held the NDA for Zofran, they were responsible for the adequacy of the label and warnings for all forms of ondansetron – whether brand name or generic.

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

12. In 2014, Plaintiff was prescribed and began taking Zofran to alleviate the symptoms of morning sickness while pregnant.

13. Subsequently, in 2014, Plaintiff's unborn child was diagnosed with severe and life-threatening fetal defects, including a severe abdominal malformation.

14. These fetal defects were the direct and proximate result of Plaintiff's exposure to Zofran.

15. On or about August 13, 2014, as a result of these fetal birth defects, Plaintiff terminated her pregnancy.

16. Plaintiff suffered severe and ongoing pain, distress, suffering, and expense as a result of the actions of the Defendant GSK through her exposure to Zofran while pregnant.

17. Had Plaintiff known the truth about the unreasonable risk of harm posed by Zofran, long concealed by GSK, she would never have taken branded or generic Zofran.

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

JURISDICTION AND VENUE

19. 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 Defendant is incorporated and has its principal place of business in a state other than the state in which Plaintiff resides.

20. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

21. Venue is proper in this Court pursuant to 28 U.S.C.§1391 because Defendants engaged in marketing, promoting, labeling, and distributing their product in each of the fifty States in the United States, and specifically including Plaintiffs' state of citizenship and the state in which Plaintiff ingested the drug and the injury occurred.

22. Additionally, venue is proper within this District pursuant to MDL Order #6, dated December 17, 2015 in MDL No. 2657**,** which allows direct filing of Zofran actions in this District.

23. Absent MDL Order No. 6, Plaintiff would have filed this case in the district court for the Northern District of New York, because the ingestion and injuries described herein occurred within that District.

24. At all times herein mentioned, GSK conducted, and continues to conduct, a substantial amount of business activity and has committed a tort, in whole or in part, in this district.

GSK is registered to conduct business in this district and also engaged in interstate commerce when they advertised, promoted, supplied, and sold pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in this district. GSK's plan to misleadingly market Zofran for pregnancy-related morning sickness was executed nationwide, including in this district.

PARTIES

25. Plaintiff, Alexis Ostrander, is a citizen of the United States. Plaintiff resides in Cerro Gordo, Piatt County, Illinois.

26. 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.

27. 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.

28. At all relevant times, GSK conducted business in Illinois and New York and derived substantial revenue from products, including Zofran, sold in Illinois and New York.

PERTINENT BACKGROUND ON ZOFRAN

29. 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.)

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

31. 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).

32. 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.

33. 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).

34. 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).

35. 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)

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

37. 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.

38. 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.

39. 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.

40. 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.

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

GSK's Knowledge That Zofran Presents an Unreasonable Risk of Harm to Fetuses That Are Exposed to It In Utero

Preclinical Studies

42. 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.

43. The placental transfer of Zofran during human pregnancy at concentrations high

enough to cause congenital malformations was 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.

44. 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).

45. 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.

46. 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.

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

48. Study No. L10649 Oral was a 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."

49. 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 teratogen in humans, but animal studies involving the drug failed to demonstrate such an increased risk of birth defects in animals. GSK conducted studies of thalidomide and its toxicity before GSK developed Zofran and before it marketed Zofran for the treatment of morning sickness in pregnant women. Moreover, since at least 1993, GSK has stated in its prescribing information for Zofran that "animal reproduction studies are not always predictive of human response." Therefore, GSK has been aware since at least when it began marketing and selling Zofran that GSK could not responsibly rely on its animal studies as a basis for promoting Zofran use in pregnant women. But that is what

GSK did.

Early Reports to GSK of Zofran-Related Birth Defects

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

51. 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.

52. 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.

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

54. 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.

55. 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 Fetuses That Were Exposed to Zofran In Utero

56. Epidemiology is a branch of medicine focused on studying the causes, distribution,

and control of diseases in human populations.

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

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

59. The Pasternak Study included data from the Danish National Birth Registry and examined the use of Zofran during pregnancy and risk of adverse fetal outcomes. Adverse fetal outcomes were defined as: spontaneous abortion, stillbirth, any major birth defect, pre-term delivery, low birth weight, and small size for gestational age. There were 608,385 pregnancies between January 2004 and March 31, 2011 examined. The unexposed group was defined as women who did not fill a prescription for ondansetron during the exposure time window. The exposure time window was defined as the first 12 week gestational period. Notably, the median fetal age at first exposure to Zofran was ten weeks, meaning that half of the cases were first exposed

to Zofran after organogenesis (organ formation). This characteristic of the study led to an under-reporting of the actual risk of prenatal Zofran exposure. The study's supplemental materials indicated that women taking Zofran during the first trimester, compared to women who did not take Zofran, were 22% more likely to have offspring with a septal defect, 41% more likely to have offspring with a ventricular septal defect and greater than four-times more likely to have offspring with atrioventricular septal defect.

60. The Andersen Study was also based on data collected from the Danish Medical Birth Registry and the National Hospital Register, the same data examined in the Pasternak Study. The Andersen study examined the relationship between Zofran use during the first trimester and subgroups of congenital malformations. Data from all women giving birth in Denmark between 1997 and 2010 were included in the study. A total of 903,207 births were identified in the study period with 1,368 women filling prescriptions for Zofran during the first trimester. The Andersen Study therefore used a larger data set (13 years) compared to the Pasternak Study (seven years). Exposure to the drug was also defined as filling a prescription during the first trimester, and prescription data were obtained from the National Prescription Registry. The Andersen study reported that mothers who ingested Zofran during their first- trimester of pregnancy were more likely to have a child with a congenital heart defect, and had a two- to four-fold greater risk of having a baby with a septal cardiac defect.

61. The Danielsson Study investigated risks associated with Zofran use 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 significant elevated risk for cardiovascular defects for mothers taking Zofran versus those who did not. The results reported that the mothers who took Zofran during early pregnancy had a 62% increased risk of having a baby with a cardiovascular defect. Further, mothers who took Zofran during pregnancy had a greater than two-fold increased risk of having a baby with a septal cardiac defect, compared to mothers who did not take Zofran during pregnancy.

62. In summary, since at least 1992, GSK has had mounting evidence showing that Zofran presents an unreasonable risk of harm to babies who are exposed to the drug during pregnancy. GSK has been aware that Zofran readily crosses human placental barriers during pregnancy. GSK has also been aware that the animal studies of Zofran cannot reliably support an assertion that Zofran can be used safely or effectively in pregnant women. Since 1992, GSK has received hundreds of reports of major birth defects associated with prenatal Zofran exposure. GSK also has had actual and/or constructive knowledge of the epidemiological studies reporting that prenatal Zofran exposure can more than double the risk of developing 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

63. 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).

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

65. 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.*

66. 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).

67. 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. Wilborn and her prescribing healthcare provider.

68. 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.

69. By contrast, the U.S. Supreme Court has declared that a generic drug manufacturer cannot unilaterally add to or strengthen a contraindication, warning, precaution or adverse reaction. *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 660 (Ala. 2014) (citing *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (U.S. 2011).

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

required to make the same additions. *Id.* at 660-661.

71. 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."

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

73. 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.

74. 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."

75. 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**."

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

77. 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 has established five categories to indicate the potential a drug has 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).

78. 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. Additionally, epidemiology studies and placental-transfer studies further demonstrate 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.

79. 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."

80. 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.

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

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

82. However, the more than six million annual pregnancies in the United States since 1991 with an estimated 70-85% incidence of pregnancy-related nausea, combined with an absence of a prescription medication approved by the FDA for pregnancy-related nausea, presented an extremely lucrative business opportunity for GSK to expand its sales of Zofran. 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.

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

women.

84. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) notified GSK that the FDA had become aware of GSK's promotional materials for Zofran that violated the Federal Food Drug and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance." (FDA Ltr. to Michele Hardy, Director, Advertising and Labeling Policy, GSK, March 9, 1999.)

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

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

87. GSK blatantly disregarded this mandate by the FDA. For example, in 2002, GSK's marketing materials to Ob/Gyn practitioners emphasized Zofran's "Pregnancy Category B" designation on the very first page of the marketing material, creating a false impression that the safety of use in pregnancy has been established. GSK's materials failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran treatment during pregnancy.

88. GSK's promotion of Zofran for use in pregnancy eventually led to a federal governmental investigation. On July 2, 2012, the Department of Justice announced that GSK "agreed to plead guilty and pay $3 billion to resolve its criminal and civil liability arising from the

company's unlawful promotion of certain prescription drugs," which included Zofran among others. DOJ Press Release, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012).

89. Part of GSK's civil liability to the government included payments arising from the facts that: (a) GSK promoted Zofran and disseminated false representations about the safety and efficacy of Zofran concerning pregnancy-related nausea and hyperemesis gravidarum, a severe form of morning sickness; and (b) GSK paid and offered to pay illegal remuneration to health care professionals to induce them to promote and prescribe Zofran.

PLAINTIFF'S EXPOSURE TO ZOFRAN

90. Plaintiff Alexis Ostrander became pregnant in 2014.

91. To alleviate the symptoms of morning sickness and prevent them from recurring, Plaintiff was prescribed, and began taking, Zofran or its generic equivalent.

92. In July 2014, Plaintiff learned, through diagnostic testing, that her unborn child had developed severe physical malformations, including severe and life-threatening abdominal defects.

93. These malformations were the direct and proximate result of prenatal exposure to Zofran.

94. As a result of these severe and life-threatening defects to her unborn child, Plaintiff terminated her pregnancy on or about August 13, 2014.

95. Plaintiff was unaware of the dangers associated with Zofran or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during pregnancy.

96. Had Plaintiff and/or her healthcare providers known of the increased risk of birth

defects associated with Zofran, she would not have taken branded or generic Zofran during pregnancy, and her pregnancy would have progressed to term with a healthy child.

97. Had Plaintiff known of the increased risk of birth defects associated with Zofran, and had she not been misled by GSK's promotion of the drug's purported safety benefits for use during pregnancy, on which she reasonably relied, Plaintiff would not have taken branded or generic Zofran during pregnancy and Baby would have been born a healthy child.

98. As a direct and proximate result of GSK's conduct, Plaintiff has suffered and incurred harm including severe and ongoing pain and suffering, physical harm, mental anguish, medical expenses and other economic and noneconomic damages.

99. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Zofran caused the appreciable harm sustained by her and set forth herein.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

100. Plaintiff repeats, reiterates and realleges 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.

101. 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.

102. GSK failed to exercise ordinary care and failed to comply with existing standards of care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk

of dangerous birth defects, as well as other severe personal injuries which are permanent and lasting in nature, or fatal, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

a. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety risks of Zofran for treating pregnant women while promoting the use of Zofran and providing kickbacks 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 Plaintiff, the public, the medical and healthcare profession, ondansetron ANDA holders, and the FDA of the dangers of Zofran to 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, ondansetron ANDA holders 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 using the drug for that condition outweigh any putative benefit; and

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

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

105. GSK knew or should have known that consumers such as Plaintiff would foreseeably use the generic form of Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

106. 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.

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

108. Had Plaintiff not taken branded or generic Zofran, her baby would not have suffered those injuries and damages as described herein with particularity.

109. As a result of the foregoing acts and omissions, Baby was caused to suffer serious fatal birth defects.

110. Plaintiff also has sustained severe emotional distress and suffering as a result

GSK's wrongful conduct and the death of her child.

111. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health, incidental and related expenses.

112. 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, justifying an award of punitive damages.

SECOND CAUSE OF ACTION
(NEGLIGENCE PER SE)

113. Plaintiff repeats, reiterates and realleges 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.

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

115. GSK failed to exercise ordinary care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, or fatal, 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 ordinary care and violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b, 21 C.F.R. §§ 201.57, 201.128, and Ark. Code § 4-49-107, *et seq.* in particular.

117. The laws violated by GSK were designed to protect Plaintiff, her baby, and similarly situated persons and protect against the risks and hazards that have actualized in this case. Therefore, GSK's conduct constitutes negligence per se.

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

119. GSK knew or should have known that consumers such as Plaintiff would foreseeably use the generic form of Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

120. 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.

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

122. Had Plaintiff not taken branded or generic Zofran, her baby would not have suffered those injuries and damages as described herein with particularity.

123. As a result of the foregoing acts and omissions, Baby was caused to suffer serious fatal birth defects.

124. Plaintiff also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the death of her child.

125. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health,

incidental and related expenses.

126. 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, justifying an award of punitive damages.

THIRD CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

127. Plaintiff repeats, reiterates and realleges 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.

128. 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.

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

130. Prescribing physicians, health care providers and mothers-to-be, neither knew, nor

had reason to know at the time of their use of Zofran of the existence of the aforementioned defects. Ordinary consumers would not have recognized the potential risks or side effects for which GSK failed to include appropriate warnings, and which GSK masked through unbalanced promotion of Zofran specifically for treatment of pregnant women.

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

132. As a direct and proximate result of the defective nature of Zofran, Baby was caused to suffer serious fatal birth defects.

133. Plaintiff also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the death of her child.

134. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health, incidental and related expenses.

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

FOURTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

136. Plaintiff repeats, reiterates and realleges 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.

137. GSK falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff and her providers, that:

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

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

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

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

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

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

140. GSK made these representations with the intent of defrauding and deceiving the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, including Plaintiff and her providers, to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy-related nausea, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff herein.

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

142. In reasonable reliance upon said representations, Plaintiff's prescriber was induced to prescribe Zofran and/or its generic form to her and recommend the drug as safe for treating pregnancy-related nausea, and Plaintiff was induced to and did use the generic form of Zofran to treat pregnancy-related nausea. Had GSK not made the foregoing express and implied false statements about the product, Plaintiff's physician would not have recommended or prescribed Zofran and Plaintiff would not have used the product.

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

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

145. GSK knew or should have known that consumers such as Plaintiff would foreseeably use the generic form of Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

146. As a result of the foregoing acts and omissions, Baby was caused to suffer fatal birth defects.

147. Plaintiff also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the death of her child.

148. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health, incidental and related expenses.

149. 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, justifying an award of punitive damages.

FIFTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

150. Plaintiff repeats, reiterates and realleges 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.

151. In representations to Plaintiff's healthcare providers, expectant mothers including

Plaintiff, generic ANDA holders, and the FDA, GSK fraudulently concealed and intentionally omitted the following material facts:

a. GSK was illegally paying and offering to pay doctors remuneration to promote and prescribe Zofran;

b. Zofran had not (and has not) been tested or studied in pregnant women at all;

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

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

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

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

g. GSK's internal data and information associated Zofran use during pregnancy with birth defects.

152. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran for pregnancy-related nausea was made purposefully, willfully, wantonly, and/or recklessly, to mislead physicians, hospitals and healthcare providers, and expectant mothers, including Plaintiff, into reliance, continued use of branded or generic Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

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

154. Plaintiff and her providers reasonably relied on GSK's promotional statements concerning Zofran's asserted safety and efficacy in pregnant women, from which GSK negligently, fraudulently and/or purposefully omitted material facts.

155. As a result of the foregoing acts and omissions, Baby was caused to suffer serious fatal birth defects.

156. Plaintiff also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the death of her child.

157. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health, incidental and related expenses.

158. 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, justifying an award of punitive damages.

SIXTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

159. Plaintiff repeats, reiterates and realleges 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 falsely and negligently represented to the medical community and expectant mothers, including Plaintiff and her providers, that:

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

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

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

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

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

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

163. Had GSK not made express and implied false statements, or had revealed all material information about Zofran, Plaintiff's providers would not have prescribed it and Plaintiff would not have used its generic equivalent.

164. As a result of the foregoing acts and omissions, Baby suffered serious fatal birth defects.

165. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health, incidental and related expenses.

166. Plaintiff also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the death of her child.

167. 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, justifying an award of punitive damages.

SEVENTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

168. Plaintiff repeats, reiterates and realleges 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.

169. Defendants expressly warranted that:

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

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

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

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

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

171. Plaintiff and her healthcare providers did rely on the express warranties of the GSK herein.

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

173. GSK knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Zofran was not safe and fit for the use promoted, expressly warranted and intended by GSK, and, in fact, it produced serious injuries to the pregnant women and their babies, which injuries were not accurately identified and disclosed by GSK.

174. As a result of the foregoing acts and omissions, Baby was caused to suffer serious

and dangerous side effects that led to her death.

175. Plaintiff also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the death of her child.

176. 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, justifying an award of punitive damages.

EIGHTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY
OF MERCHANTABILITY AND FITNESS FOR PARTICULAR USE)

177. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

179. GSK's product was not fit for the ordinary purpose for which such goods were used. It was defective in design and its failure to provide adequate warnings and instructions, and was unreasonably dangerous. GSK's product was dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including Plaintiff and her medical providers.

180. GSK breached its implied warranties because the product was not safe, not

adequately packaged and labeled, did not conform to representations GSK made, and was not properly usable in its current form according to the labeling and instructions provided.

NINTH CAUSE OF ACTION
(UNFAIR AND DECEPTIVE TRADE PRACTICES)

181. Plaintiff repeats, reiterates and realleges 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.

182. By reason of its conduct as alleged herein, Defendant violated the provisions of applicable State law against unfair and deceptive trade practices by, among other things:

a. Engaging in unfair trade practices as defined in the statute by making false and misleading oral and written statements that had the capacity, tendency, or effect of deceiving or misleading physicians, patients and consumers;

b. Engaging in unfair trade practices as defined in the statute by making representations that their products had an approval, characteristic, ingredient, use or benefit, which it did not have, including but not limited to statements concerning the health consequences of the use of Defendant's product Zofran;

c. Engaging in unfair trade practices as defined in the statute by failing to state material facts, the omission of which deceived or intended to deceive, including but not limited to, facts relating to the health consequences of the use of Defendant's product Zofran;

d. Engaging in unfair trade practices as defined in the statute through deception, fraud, misrepresentation, and knowing concealment, suppression and omission of material facts with the intent that physicians, patients and consumers rely upon the same in connection with the use of Defendant's product Zofran.

183. These violations of State law by Defendant proximately caused Plaintiff's injuries and damages as described herein.

TENTH CAUSE OF ACTION
(WRONGFUL DEATH)

184. Plaintiff repeats, reiterates and realleges 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.

185. GSK marketed Zofran to Plaintiff's physicians, and GSK knew or had reason to know of the unreasonable dangers and defects in their Zofran product, Plaintiff and her physicians would use the product, and that Baby would suffer lethal injuries as a result of her prenatal exposure to Zofran.

186. GSK owed Plaintiff the duty to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge, and to produce and market Zofran in as safe a manner and condition as possible.

187. Specific defects, as specified above in this Complaint, in the Zofran product, rendered it defective and unreasonably dangerous.

188. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, GSK breached its duty to Plaintiff. Such breach exhibited a reckless disregard for the safety of others and willful and wanton conduct.

189. As the direct, producing, proximate and legal cause and result of GSK's breach of its duties, Baby died on or about August 13, 2014.

190. As the direct, producing, proximate and legal cause and result of GSK's breach of its duties, Plaintiff, individually and as a representatives of Decedent, has been injured and has incurred economic and non-economic damage, including but not limited to medical and hospital expenses in the past, past mental pain and suffering, funeral and burial expenses, loss of financial

support, services, love, companionship, comfort, case, assistance, protection, affection, society, and moral support of her deceased daughter.

191. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

192. GSK is estopped from relying on any statutes of limitation because of its fraudulent concealment and misrepresentations of the true facts concerning the risks of Zofran. GSK was, at all relevant times, aware of the nature and existence of the risks of Zofran, but at all times has continued to manufacture, certify, market, advertise, promote off-label and sell Zofran without revealing the true facts concerning the defects, in order to profit from more sales of Zofran, to avoid bad publicity, and to avoid expensive recalls. The true facts about the risks of birth defects continue to be concealed from the public, including Plaintiff.

193. GSK's fraudulent concealment scheme discussed above, includes, but it not limited to, intentionally covering up and refusing to publicly disclose risks of prenatal exposure to Zofran. Through such acts of fraudulent concealment, GSK was able to actively conceal from the public for years the truth about the risk of prenatal injuries, thereby tolling the running of any applicable statute of limitations.

194. Through such acts of fraudulent concealment, GSK has successfully concealed from the public facts necessary to support the claims herein. Plaintiff was and continues to be prevented from knowing and having knowledge of such unlawful, unfair, fraudulent, and deceptive conduct, or of facts that might have led to the discovery thereof.

195. Given GSK's past and continuing denials of, and concealment of, the existence of any prenatal harm caused by Zofran, and GSK's repeated and past and continuing representations that Zofran is safe for pregnant women, GSK may not assert any statute of

limitations defense with respect to Plaintiff's wrongful death (or any other) claims asserted herein.

ELEVENTH CAUSE OF ACTION
(NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS)

196. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

197. Defendant negligently inflicted severe emotional distress upon the Plaintiff by its negligent and careless actions, including, but not limited to:

a. Producing, manufacturing, formulating, designing, and/or advertising ondansetron to pregnant women to treat morning sickness without sufficiently, thoroughly, and/or adequately testing it for that purpose;
b. Selling ondansetron to pregnant women without performing sufficient/adequate testing to determine the full range of dangers to pregnant women;
c. Failing to warn Plaintiff, the general public, healthcare providers, and the FDA of the dangers associated with using ondansetron during pregnancy;
d. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably use ondansetron;
e. Failing to test ondansetron and failing to adequately, sufficiently and properly test it for use by pregnant women;
f. Negligently advertising and recommending the use of ondansetron, Plaintiff,

the general public, and healthcare providers without sufficient knowledge as to its dangerous propensities in pregnant women;

g. Negligently representing that ondansetron was safe for use by pregnant women, when, in fact, it was unsafe;

h. Negligently representing that ondansetron was equally as safe and effective as other available forms of treatment for morning sickness in pregnant women;

i. Negligently designing ondansetron in a manner which was dangerous to users, including Plaintiff;

j. Knowingly concealing that ondansetron was unsafe, dangerous, and/or non-conforming with FDA regulations from Plaintiff, the general public, and healthcare providers;

k. Improperly concealing and/or misrepresenting information regarding the risks and dangers posed by using ondansetron during pregnancy.

198. Had Plaintiff not taken ondansetron, her child would not have suffered those injuries and damages as described hereinabove.

199. Plaintiff has sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the death of her child.

200. As a result of the foregoing acts and omissions, Plaintiff did incur medical, health, incidental and related expenses.

201. 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, justifying an award of punitive damages.

TWELFTH CAUSE OF ACTION
(LOSS OF CONSORTIUM)

202. 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.

203. As a direct and proximate result of Defendant's negligence and wrongful conduct, Plaintiff has been deprived of the society, love, comfort, affection, companionship, solace, moral support, care and services, of her child and is entitled to recovery for said loss.

204. Plaintiff seeks all damages available against GSK on account of the loss of her daughter's consortium.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

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 an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;

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: July 25, 2016

/s/Steven D. Davis_____
Steven D. Davis, IL 6281263
TORHOERMAN LAW LLC
101 W. Vandalia St., Ste. 350
Edwardsville, IL 62025
Telephone: (618) 656-4400
Facsimile: (618) 656-4401
sdavis@thlawyer.com

ATTORNEYS FOR PLAINTIFF

JS 44 (Rev. 11/15)

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

Alexis Ostrander, Individually and on behalf of her deceased daughter Baby Girl O.

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
TorHoerman Law LLC, 101 West Vandalia Street, Suite 350, Edwardsville, IL 62025 (618) 656-4400

DEFENDANTS

GlaxoSmithKline LLC

County of Residence of First Listed Defendant
(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)*

❒ 110 Insurance	**PERSONAL INJURY**	**PERSONAL INJURY**	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability			❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		**PROPERTY RIGHTS**	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	**PERSONAL PROPERTY**		❒ 820 Copyrights	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud		❒ 830 Patent	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending		❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 710 Fair Labor Standards Act	**SOCIAL SECURITY**	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 720 Labor/Management Relations	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 740 Railway Labor Act	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 751 Family and Medical Leave Act	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise			❒ 790 Other Labor Litigation	❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
			❒ 791 Employee Retirement Income Security Act	❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
REAL PROPERTY	**CIVIL RIGHTS**	**Habeas Corpus:**			❒ 893 Environmental Matters
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	❒ 463 Alien Detainee		**FEDERAL TAX SUITS**	❒ 895 Freedom of Information Act
❒ 220 Foreclosure	❒ 441 Voting	❒ 510 Motions to Vacate Sentence		❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 896 Arbitration
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 530 General		❒ 871 IRS—Third Party 26 USC 7609	❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 535 Death Penalty			❒ 950 Constitutionality of State Statutes
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	**Other:**	❒ 462 Naturalization Application		
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	❒ 540 Mandamus & Other	❒ 465 Other Immigration Actions		
	❒ 448 Education	❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

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:
Personal Injury; products liability

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 Judge F. Dennis Saylor DOCKET NUMBER MDL 2657

DATE
07/25/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/Steven D. Davis

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** Alexis Ostrander, Individually and on behalf of her deceased daughter Baby Girl O. v. GlaxoSmithKline LLC

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

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

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

☑ **III.** **120, 150, 151, 152, 153, 195, 210, 220, 245, 310, 315, 330, 340, 345, 350, 355, 360, 365, 367, 368, 375, 376, 385, 400, 422, 423, 450, 460, 462, 463, 465, 480, 490, 510, 530, 540, 550, 555, 625, 690, 751, 791, 861-865, 890, 896, 899, 950.**

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

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

MDL 2657

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

YES ☐ **NO** ☑

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

YES ☐ **NO** ☑

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

YES ☐ **NO** ☐

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

YES ☐ **NO** ☑

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

YES ☐ **NO** ☑

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

Eastern Division ☐ **Central Division** ☐ **Western Division** ☐

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

Eastern Division ☐ **Central Division** ☐ **Western Division** ☐

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

YES ☐ **NO** ☑

(PLEASE TYPE OR PRINT)
ATTORNEY'S NAME Steven D. Davis
ADDRESS 101 West Vandalia Street, Suite 350, Edwardsville, IL 62025
TELEPHONE NO. (618) 656-4400