IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
SOUTHWESTERN DIVISION

Civil No. _____

Angela Kutzer and Bryan Kutzer, Individually and as Parents and Natural Guardians of G.K., a Minor Plaintiffs, vs. GlaxoSmithKline, LLC, Defendant.	**COMPLAINT AND JURY DEMAND**

*** *** ***

COME NOW Plaintiffs, Angela Kutzer and Bryan Kutzer, individually and on behalf of their son, G.K., a minor, ("plaintiffs"), who by and through the undersigned counsel hereby submit this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "defendant") for compensatory damages, equitable relief, and such other relief deemed just and proper arising from the injuries to G.K. as a result of his prenatal exposures to the prescription drug Zofran®, also known as ondansetron. In support of this Complaint, plaintiffs allege the following:

INTRODUCTION

I.

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 treatment in cancer patients.

II.

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

III.

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 drugs 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.

IV.

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

V.

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.

VI.

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

VII.

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).

VIII.

Around the same time, however, GSK entered civil settlements with the United States that included more than $3 billion in payments to the federal government for its illegal marketing of various drugs, including Zofran specifically.

IX.

GSK's civil settlement agreement with the United States reports GSK's settlement of claims included that GSK:

I) "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)"

II) "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]"

III) "offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran"

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

X.

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

XI.

Plaintiffs' minor child, G.K., was born in 2007 with congenital defects after his mother, plaintiff Angela Kutzer, was prescribed and began taking Zofran beginning early in her first trimester of pregnancy and took it continuously during her pregnancy to alleviate and prevent the symptoms of morning sickness, both intravenously and in pill form.

XII.

According to G.K.'s treating physician records, G.K. suffers from congenital unilateral renal agenesis (a missing kidney), congenital unilateral absence of the vas deferens, lack of the necessary connective tissues to allow for a kidney transplant, kidney damage and other unknown injuries, all of which are attributable to plaintiff Angela Kutzer's ingestion of Zofran during her pregnancy with G.K.

XIII.

G.K. was continuously exposed to Zofran in utero during the periods when each of these tissues was forming and susceptible to developmental insult from environmental exposure.

XIV.

G.K. has no family history of any of the conditions from which he suffers. Angela and Bryan Kutzer both have both of their kidneys, and upon information and belief so does every other family member. In addition, G.K. has an older brother who was born healthy and vibrant after Ms. Kutzer carried him for a full-term pregnancy during which she does not believe she ingested any Zofran.

XV.

In October of 2013, G.K. suffered an injury to his one remaining kidney due to an accident at the Kutzer home. Upon presenting G.K. at the emergency room in Bismarck, North Dakota at St. Alexius Hospital, Angela and Bryan Kutzer learned for the first time that G.K. had only one kidney. The only kidney G.K. was born with, which was injured in the accident, was significantly damaged and as a result of that accident and G.K. had to be transported via air care to Minneapolis for hospitalization and extensive treatment. G.K. now only has approximately 38% function of his one remaining kidney. Had G.K. been born with two functioning kidneys, which is not the case because of Zofran, his current health situation would be much less debilitating and significantly less grave. But as it stands, having a single kidney with 38% functioning and no second kidney (low functioning single kidney) represents a serious threat to G.K.'s very life, health, and enjoyment of life. Plaintiffs have incurred significant out of pocket costs and expenses due to G.K.'s air transfer to and treatment in Minneapolis, along with the additional anxiety, fear and suffering experienced by G.K. traveling several hundred miles from his home. Had G.K. been born with a second kidney, despite the injury, none of the additional and highly specialized treatment in Minneapolis would have been incurred as G.K. would have been treated successfully in his home town, Bismarck.

XVI.

G.K.'s birth defects and low functioning single kidney impair his development and enjoyment of a normal life at home and at school due to substantial risks of injury or death which can be caused by the slightest aggravation or injury. G.K.'s physicians have told G.K he can never again in his life play sports or perform the activities he routinely took part in prior to the discovery he was born with only one kidney. Prior to 2013, G.K. was very active participating in soccer and basketball and was previously a very active boy. In addition, G.K. will be completely unable or will have extreme difficulty producing children when he is a grown man due to not having a fully functioning vas deferens. G.K. may in fact not be able to have any normal male sexual function at all.

XVII.

Had plaintiffs known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, plaintiff Angela Kutzer would have never taken Zofran, and her child G.K. would never have been injured as described herein.

XVIII.

Plaintiffs bring claims for compensatory damages, as well as equitable relief both for themselves and their minor child G.K., and also in an effort to ensure that similarly situated mothers-to-be are fully informed about the risks, benefits and alternatives in relation to 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

XIX.

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

XX.

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

XXI.

At all times herein mentioned, GSK conducted, and continues to conduct, a substantial amount of business activity and has committed a tort, in whole or in part, in this judicial district. GSK is registered to conduct business in this district, with a Resident Agent located in Bismarck, ND, and 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. Although GSK's plan to misleadingly market Zofran for pregnancy was devised outside this district and state, it was executed nationwide, including in this district and state.

PARTIES

XXII.

Plaintiffs, Angela and Bryan Kutzer, are citizens of the United States. They are the mother and father of G.K., who lives with them. Angela and Bryan Kutzer are married. Plaintiffs currently reside in Bismarck, North Dakota.

XXIII.

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.

XXIV.

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.

XXV.

At all relevant times, GSK conducted business in the state of North Dakota and has derived substantial revenue from products, including Zofran, sold in this state.

PERTINENT BACKGROUND ON ZOFRAN

XXVI.

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.)

XXVII.

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

XXVIII.

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).

XXIX.

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 areas 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.

XXX.

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).

XXXI.

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).

XXXII.

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)

XXXIII.

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

XXXIV.

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.

XXXV.

A team of the FDA's physicians, statiscians, 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.

XXXVI.

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.

XXXVI.

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.

XXXVII.

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

GSK'S knowledge that Zofran presents an unreasonable risk of harm to babies who are exposed to it during pregnancy

Preclinical studies

XXXVIII.

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.

XXXIX.

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.

XL.

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).

XLI.

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.

XLII.

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.

XLIII.

Study No. R10590 Oral Segment II teratological study of rats. Four groups of 30 pregnant rats (120 total) were given Zofran orally at doses of 0, 1, 4 and 15 mg/kg/day, respectively. Subdued behavior, labored breathing, which is a symptom of congenital heart defects, and dilated pupils were observed in the 15 mg/kg/day group. Body weight, gestational

duration and fetal examinations were reported as normal, but "slight retardation in skeletal ossification" was noted in the offspring.

XLIV.

Study No. L10649 Oral Segment II teratological study of rabbits. Four groups of 14-18 pregnant rabbits (56-64 total) were given Zofran orally at doses of 0, 1, 5.5 and 30 mg/kg/day. The study reported lower maternal weight gain in all of the exposed groups, as well as premature delivery and "total litter loss," referring to fetal deaths during pregnancy in the 5.5 mg/kg/day group. Examination of the fetuses showed "slight developmental retardation as evident by incomplete ossification or asymmetry of skeleton."

XLV.

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. But that is what GSK did.

Early reports of GSK of Zofran-related birth defects to GSK

XLVI.

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

XLVII.

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.

XLVIII.

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.

XLIX.

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

L.

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.

LI.

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

Epidemiology studies examining the risk of congenital heart defects in babies who were exposed to Zofran during pregnancy

LII.

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

LIII.

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").

LIV.

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.

LV.

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.

LVI.

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.

LVII.

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.

LVIII.

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

LIX.

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).

LX.

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

LXI.

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.*

LXII.

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).

LXIII.

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. Kutzer and her prescribing healthcare provider.

LXIV.

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.

LXV.

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.

LXVI.

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."

LXVII.

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.

LXVIII.

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.

LXIX.

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."

LXX.

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

LXXI.

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.

LXXII.

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).

LXXIII.

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).

LXXIV.

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.

LXXV.

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."

LXXVI.

In summary, beginning years before plaintiff G.K. 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 promote it for use in pregnant women. This rendered the warnings accompanying Zofran inadequate and defective.

LXXVII.

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

GSK's fraudulent, off-label promotion of Zofran for the treatment of morning sickness in pregnant women

LXXVIII.

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

LXXIX.

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.

LXXX.

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.

LXXXI.

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.

LXXXII.

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.)

LXXXIII.

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.

LXXXIV.

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.**"

LXXXV.

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.

LXXXVI.

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.

LXXXVII.

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.

LXXXVIII.

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.

LXXXIX.

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.

XC.

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.

XCI.

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).

XCII.

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.

XCIII.

GSK's 2012 civil settlement with the United States covered improper promotional conduct that was part of an overarching plan to maximize highly profitable Zofran sales without due regard to laws designed to protect patient health and safety. Another component of that plan led to a separate $150 million settlement between GSK and the United States in 2005. In or around 1993, a GSK marketing document sent to all of its sales and marketing personnel nationwide advised that they should emphasize to medical providers not only the benefits of Zofran but also the financial benefits to the providers by prescribing Zofran. Specifically, "[b]y using a 32 mg bag [of Zofran], the physician provides the most effective dose to the patient and increases his or her profit by $___ in reimbursement." GSK's marketing focus on profits to the prescribers misleadingly aimed to shift prescribers' focus from the best interests of patients to personal profit. In this regard, GSK marketed Zofran beginning in the 1990s as "convenient" and offering "better reimbursement" to prescribers. GSK detailed this plan in a marketing document for its Zofran premixed IV bag entitled "Profit Maximization – It's in the Bag." Upon information and belief, GSK's conduct in this paragraph continued until the DOJ began investigating it in the early 2000s.

Plaintiffs' exposures to Zofran

XCIV.

Plaintiff Angela Kutzer is the mother and natural guardian of G.K.

XCV.

To alleviate and prevent the symptoms of morning sickness, plaintiff Angela Kutzer was prescribed Zofran by her treating doctors during her pregnancy with G.K. and took at least the following dosages of Zofran:

DATE	METHOD	DOSAGE	LOCATION
10/22/2006	IV (Ondansotron)	4 mg	St. Alexius Medical Center – ER
10/22/2006	Oral (Zofran)	5 tabs/4 mg ea	Gateway Healthmart Pharmacy
11/07/2006	IV (Zofran)	8 mg	Mid Dakota Clinic
11/11/2006	Oral (Zofran)	10 tabs/4 mg ea	Gateway Healthmart Pharmacy
11/21/2006	Oral (Zofran)	5 tabs/4 mg ea	Gateway Healthmart Pharmacy
12/01/2006	IV (Zofran)	4 mg	Mid Dakota Clinic
03/28/2007	Oral (Ondansetron)	10 tabs/4 mg ea	Gateway Healthmart Pharmacy

XCVI.

G.K. was born in 2007.

XCVII.

According to G.K.'s treating physician records, G.K. has unilateral renal agenesis (meaning he is missing one kidney), congenital unilateral absence of the vas deferens, kidney damage, including but not limited to a missing kidney, and other unknown injuries. G.K.'s

remaining kidney, the only kidney he will have the rest of his life, currently functions at only 38 percent.

XCVIII.

G.K. was exposed to Zofran in utero during periods when each of these tissues was forming and susceptible to developmental insult from environmental exposure. Ms. Kutzer was given large doses of Zofran through I.V. administration on several occasions during her first and third trimesters of pregnancy with G.K. at St. Alexius Medical Center in Bismarck, North Dakota.

XCIX.

Missing kidneys can potentially be genetic, however, Angela Kutzer, Bryan Kutzer, and both of each of their parents, and G.K.'s grandparents, upon information and belief have both kidneys. G.K. has no family history of any of the conditions from which he suffers. In addition, G.K. has a brother who was born healthy and vibrant after Ms. Kutzer carried him for a full-term pregnancy during which she did not ingest any Zofran.

C.

Plaintiffs learned of G.K.'s condition in October 2013 when G.K. fell from a TV tray stand in plaintiffs' basement. Immediately following the fall, he was diagnosed with a grade 4 of a possible 5 injury to his only kidney. It was at that time, when G.K. was six years old, medical personnel and plaintiffs learned G.K. was missing a kidney, among other defects. Due to the danger of kidney damage since G.K. has only one kidney, G.K. was life-flighted from Bismarck to Minneapolis following the accident. He was hospitalized for two weeks and requires regular care and monitoring of his damaged kidney to this day. If the functioning of G.K.'s only kidney decreases to 25%, G.K. will potentially require kidney dialysis for the rest of his life. Had G.K.

been born with two kidneys the care and treatment provided to him in 2013, since that time, and in the future, would not have been as extensive or costly as it has been and will be required into the future.

CI.

Plaintiff Angela Kutzer was unaware of the dangerousness of Zofran or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during pregnancy.

CII.

Had plaintiff Angela Kutzer 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), Ms. Kutzer would not have taken Zofran during pregnancy and G.K. would not have been born with congenital malformations.

CIII.

As a direct and proximate result of GSK's conduct, plaintiffs Angela and Bryan Kutzer and their son G.K. 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, care and treatment than had they not been exposed to Zofran.

CIV.

Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that GSK's wrongful conduct caused the appreciable harm sustained by G.K. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful conduct that caused the

injuries at an earlier time. Plaintiffs did not suspect, nor did plaintiffs have reason to suspect, the tortious and otherwise wrongful nature of the conduct causing the injuries, until a short time before filing of this action. Additionally, plaintiffs were prevented from discovering this information sooner because GSK has misrepresented and continues to misrepresent to the public and to the medical profession that Zofran is safe for use in pregnancy, and GSK has fraudulently and wrongfully 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 a minor.

FIRST CAUSE OF ACTION – NEGLIGENCE

CV.

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.

CVI.

GSK had a duty to exercise reasonable care, and to comply with existing standards of care, in the designing, researching, manufacturing, marketing, supplying, promoting, advertising, 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 and their unborn children to suffer unreasonable, dangerous side effects and injuries, and further including the duty to warn of any such injuries or side effects.

CVII.

GSK failed to exercise ordinary care and failed to comply with existing standards of care in the designing, researching, manufacturing, marketing, supplying, promoting, advertising,

packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew, should have known, or recklessly disregarded the fact that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, loss of function, including diminished enjoyment of life, as well as the need for lifelong medical care and treatment, monitoring and/or medications

CVIII.

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

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

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

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

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

e. Failing to adequately and correctly warn the plaintiffs, 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 plaintiffs, healthcare providers, the 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 plaintiffs, healthcare providers, the 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.

CIX.

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 Angela Kutzer.

CX.

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

CXI.

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

CXII.

Had plaintiff Angela Kutzer 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. Kutzer would never have taken Zofran.

CXIII.

As a result of the foregoing acts and omissions, G.K. has suffered and will continue 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 and care, monitoring and/or medications.

CXIV.

Plaintiffs Angela and Bryan Kutzer have also sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their child.

CXV.

As a result of the foregoing acts and omissions, plaintiff G.K. requires and will require significantly more health care and services and has incurred medical, health, incidental and related expenses and damages. Plaintiffs Angela and Bryan Kutzer are informed and believe and further allege that their child will in the future be required to obtain further medical and/or hospital care, treatment, attention, and services.

CXVI.

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

SECOND CAUSE OF ACTION – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

CXVII.

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.

CXVIII.

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

CXIX.

GSK's product Zofran was not fit for the ordinary purpose for which such goods were used. Zofran is and was defective in its design and in GSK's failure to provide adequate warnings and instructions, and is and was unreasonably dangerous to intended users, including Angela Kutzer. GSK's product Zofranwas and remains dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including plaintiff Angela Kutzer and her medical providers.

CXX.

GSK breached its implied warranties because, among other things, the product was not safe, not adequately and appropriately packaged and labeled, especially with respect to the relative non-existence of warnings, did not conform to representations made by GSK, and was

not properly or safely usable in its current form according to the labeling and instructions provided.

CXXI.

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

CXXII.

As a result of the foregoing acts and omissions, G.K. requires and will require more health care, treatment and services and has already incurred significant medical, health, incidental and related expenses. Plaintiffs Angela and Bryan Kutzer are informed and believe and further allege that G.K. will in the future be required to obtain further medical and/or hospital care, treatment, attention, and services.

CXXIII.

Plaintiffs Angela and Bryan Kutzer have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct, breach of implied warranties, and the injuries to their child.

CXXIV.

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

THIRD CAUSE OF ACTION – FRAUDULENT MISREPRESENTATION

CXXV.

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.

CXXVI.

GSK committed actual and constructive fraud. GSK committed actual fraud by misrepresenting material facts on which plaintiff Angela Kutzer and her healthcare providers acted, and in which they relied to their detriment. GSK committed constructive fraud by acting contrary to legal or equitable duties, trust, and/or confidence upon which plaintiff Angela Kutzer reasonably relied, and by failing to act as it should have. GSK's wrongful misrepresentations and misconduct constitute constructive fraud because GSK breached legal and equitable duties and violated its fiduciary and other relationships to patients and healthcare providers.

CXXVII.

GSK had a duty to exercise reasonable care to those to whom they provided product information, labeling, recommendations and warnings about Zofran and to all those relying on the information provided, including plaintiffs and their healthcare providers.

CXXVIII.

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

CXXIX.

In violations of existing standards and duties of care, GSK intentionally, knowingly, recklessly, falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including plaintiff Angela Kutzer and her providers, that:

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

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

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

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

CXXX.

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

CXXXI.

When GSK made these representations, it knew they were false or recklessly disregarded information showing they were false.

CXXXII.

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

CXXXIII.

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

CXXXIV.

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

CXXXV.

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

CXXXVI.

GSK knew or should have known, or recklessly disregarded facts showing that Zofran increases expectant mothers' risk of developing birth defects.

CXXXVII.

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

CXXXVIII.

Plaintiffs Angela and Bryan Kutzer have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their child.

CXXXIX.

As a result of the foregoing acts and omissions, plaintiff G.K. requires and will require more health care and services and has already incurred significant medical, health, incidental and

related expenses. Plaintiffs Angela and Bryan Kutzer are informed and believe and further allege that their child will in the future be required to obtain further medical and/or hospital care and treatment, attention, and services.

CXL.

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

FOURTH CAUSE OF ACTION – FRAUDULENT CONCEALMENT

CXLI.

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.

CXLII.

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

CXLIII.

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

CXLIV.

In violations of the existing standards and duties of care, in representations to plaintiff Angela Kutzer and to plaintiff Angela Kutzer's healthcare providers, expectant mothers including plaintiff Angela Kutzer and the FDA, GSK fraudulently concealed and intentionally omitted the following material facts:

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

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

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

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

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

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

g. Zofran is not safe and effective for treating pregnancy-related nausea; and
h. GSK's internal data and information signaled an association between Zofran use during pregnancy with birth defects.

CXLV.

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

CXLVI.

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

CXLVII.

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

CXLVIII.

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

CXLIX.

Plaintiffs Angela and Bryan Kutzer have also sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their child.

CL.

As a result of the foregoing acts and omissions, Plaintiff G.K. requires and will require more health care and treatment services and has already incurred significant medical, health, incidental and related expenses. Plaintiffs Angela and Bryan Kutzer are informed and believe

and further allege that their child will in the future be required to obtain further medical and/or hospital care and treatment, attention, and services.

CLI.

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

FIFTH CAUSE OF ACTION – NEGLIGENT MISREPRESENTATION

CLII.

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.

CLIII.

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

CLIV.

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

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

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

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.

CLV.

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

CLVI.

Plaintiff Angela Kutzer 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 Angela Kutzer and her providers were induced to prescribe and use GSK's product.

CLVII.

Had GSK not made express and implied false statements, or had GSK revealed all material information about Zofran, plaintiff Angela Kutzer would not have used the product and her providers would not have prescribed it.

CLVIII.

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

CLIX.

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

Angela and Bryan Kutzer are informed and believe and further allege that G.K. will in the future be required to obtain further medical and/or hospital care and treatment, attention, and services.

CLX.

Plaintiffs Angela and Bryan Kutzer have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their child.

CLXI.

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

SIXTH CAUSE OF ACTION – UNFAIR TRADE PRACTICES, FALSE ADVERTISING AND UNLAWFUL SALES OR ADVERTISING PRACTICES, N.D.C.C. § 51 VIOLATIONS

CLXII.

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.

CLXIII.

GSK engaged in trade and commerce within the state of North Dakota.

CLXIV.

The same actions that constitute GSK's negligence, breach of warranty, misrepresentations, fraud, and concealment constitute knowing, willful, purposeful, reckless, negligent, and/or wrongful violations of N.D.C.C. Chapter 51-15.

CLXV.

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

CLXVI.

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

CLXVII.

GSK failed to provide accurate disclosures and warnings of all material information before plaintiff Angela Kutzer and her providers transacted to use GSK's product.

CLXVIII.

GSK's willful, knowing, and reckless withholding of important safety information and critical product information constitutes a violation of N.D.C.C. Chapter 51-15.

CLXIX.

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

CLXX.

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

CLXXI.

The practices described herein are unfair because they offend public policy as established by statutes, they are a clear breach of common law duties, or otherwise caused substantial injury to consumers, including but not limited to plaintiff Angela Kutzer. In this regard, GSK engaged in an unconscionable course of action.

CLXXII.

GSK willfully, wantonly, recklessly, and with gross negligence, engaged in the conduct described herein, which it knew was deceptive, in the course of retail business, trade and commerce, which had and will continue to have a deleterious impact on the public interest, health and welfare.

CLXXIII.

GSK's conduct and practices described herein are violations of N.D.C.C. Chapter 51-15.

CLXXIV.

Plaintiffs have complied with the requirements of N.D.C.C. Chapter 51-15.

CLXXV.

GSK is liable to plaintiffs for all statutory, direct and consequential damages, and fees and costs, resulting from this unfair and deceptive conduct, including multiple and/or treble damages.

SEVENTH CAUSE OF ACTION – LOSS OF CONSORTIUM UNDER N.D.C.C. § 32-03.2-04 AND PURSUANT TO OTHER APPLICABLE LAW

CLXXVI.

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.

CLXXVII.

G.K. is a minor child who is dependent upon his biological parents, Angela and Bryan Kutzer, for support.

CLXXVIII.

As a direct and proximate result of GSK's negligence and wrongful conduct, Angela and Bryan Kutzer have been deprived of the society, love, affection, companionship, care and

services of their child, G.K., and are entitled to recovery for said loss and losses pursuant to N.D.C.C. § 32-03.2-04 and other applicable law.

CLXXIX.

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

EIGHTH CAUSE OF ACTION – STRICT PRODUCTS LIABILITY

CLXXX.

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.

CLXXXI.

GSK had a duty of care to design, manufacture, market, and sell non-defective and safe products, including Zofran, and to adequately warn users and their providers of defects and any dangerous side effects of Zofran.

CLXXXII.

GSK designed and manufactured the product Zofran that was and is defective and unreasonably dangerous to its intended users, including but not limited to expectant mothers such as plaintiff Angela Kutzer.

CLXXXIII.

GSK designed and prepared defective product labeling, advertisements, brochures, literature, data sheets, warnings, and the like for the product Zofran that did not adequately and appropriately warn the intended users and their providers, including but not limited to plaintiff

Angela Kutzer, of the dangers of birth defects and other harm and injuries to pregnancies and unborn children.

CLXXXIV.

Plaintiffs and the minor child G.K. have been injured and damaged by the defective and unreasonably dangerous product Zofran and by the defective Zofran labeling, advertisements, brochures, literature, data sheets, warnings, and the like.

CLXXXV.

GSK's defective and unreasonably dangerous product Zofran and GSK's failure to provide adequate and appropriate product warnings is the direct and proximate cause of injuries to plaintiffs as discussed herein.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs demand judgment against GSK on each of the above-referenced claims and causes of action 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 as allowed by North Dakota and other applicable law;

f) For compensatory damages as allowed by North Dakota and other applicable law;

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

h) For loss of consortium to G.K.'s parents, Angela and Bryan Kutzer; and

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

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and Seventh Amendment of the U.S. Constitution.

Dated this 24th day of July, 2015.

SMITH BAKKE PORSBORG
SCHWEIGERT & ARMSTRONG

By: _____

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Attorneys for Plaintiffs,
G.K., Angela and Bryan Kutzer

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS
Angela Kutzer and Brian Kutzer, individually and as Parents and Natural Guardians of G.K., a minor

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Randall J. Bakke, Smith Bakke Porsborg Schweigert & Armstrong
P.O. Box 460
Bismarck, ND 58501 (701) 258-0630

DEFENDANTS
GlaxoSmithKline, LLC

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

Attorneys *(If Known)*

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

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

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

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

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

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

TORTS

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

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

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

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

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

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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. Section 1332
Brief description of cause:
Product Liability and Negligence Claims against Drug Manufacturer of Zofran

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE DOCKET NUMBER

DATE 7/24/2015 SIGNATURE OF ATTORNEY OF RECORD Randall Bakke

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.