THE LAW OFFICES OF HARBATKIN & LEVASSEUR, P.A.
AUDWIN F. LEVASSEUR, ESQ.
DAVID M. HARBATKIN, ESQ.
616 E. Palisade Avenue, Ste 102
Englewood Cliffs, NJ 07632
T: (201) 608-5192
F: (877) 595-1825
harbatkinlevasseur@gmail.com

Attorneys for Plaintiffs

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SARO & LEE MANDOYAN, individually, And as Parent and Natural Guardian of B.M. a Minor, Plaintiffs, vs. GLAXOSMITHKLINE LLC, and DOES 1-50 INCLUSIVE. Defendants.	**CIVIL ACTION NO.** **COMPLAINT** **JURY DEMANDED**

COMPLAINT FOR DAMAGES

SARO & LEE MANDOYAN, individually and as the parents and natural guardian of B.M. a 3 year-old minor child by and through their attorneys, the Law Offices of Harbatkin & Levasseur P.A. hereby files their complaint for damages and state as follows:

INTRODUCTION

1. This action is brought on behalf of the parents of a minor child whose unprecedented heart throbbing day-to-day, hour-by-hour physical and emotional pain and suffering both individually and collectively endured to date due to the physical birth defects and injury sustained by their minor child B.M., now 3 years old, yields no other alternative action then to seek immediate redress with a Court of Law.

2. Plaintiffs' son B.M. suffered horrific injury as a result of prenatal exposure to the prescription drug Zofran, also known as Ondansetron. The prenatal exposure caused B.M to be born with a congenital disorder commonly referred to as clubfoot. Clubfoot is a congenital deformity involving one foot or both. The affected feet appear to have been rotated internally at the ankle.

3. The pharmaceutical drug in question for the present lawsuit, Zofran, is a powerful drug developed by GSK to treat only those patients who were afflicted with the most severe nausea imaginable – that suffered as a result of chemotherapy or radiation treatments in cancer patients. By selling the drug, off label as a safe and effective treatment for the very common side effect of a normal pregnancy - pregnancy-related nausea and vomiting - otherwise known as "morning sickness" without undertaken a single study on the effects of this powerful drug on a pregnant mother or her growing child *in utero*, Defendant willfully and deliberately elected to take its chances on selling Zofran downstream in the pharmaceutical market opting to take its chances on any potential side effects the drug may incur on humans.

4. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that Zofran caused the appreciable harm sustained by their son, B.M. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the injuries at

an earlier time. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, the tortious nature of the conduct causing the injuries, until a short time before filing of this action. Additionally, Plaintiffs were prevented from discovering this information sooner because GSK has misrepresented to the public and to the medical profession that Zofran is safe for use in pregnancy, and GSK has fraudulently concealed facts and information that could have led Plaintiffs to discover a potential cause of action. In all events, the statute of limitations is tolled for claims arising from injuries to minors.

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

6. GSK also knew that NDA 20-781 – Zofran (a/k/a Zofran-Zydis), an orally disintegrating tablets contains aspartame, a dietary sugar substitute, which is well known that a higher levels of ingestion can pose risk of fetal toxicity by way of active placental transport.

7. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date. GSK never disclosed these reports to pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological studies that have demonstrated an elevated risk of developing birth defects such as those suffered in this case. GSK has not disclosed this to pregnant women or their physicians. Instead, GSK sales

representatives specifically marketed and promoted Zofran as a morning sickness drug throughout the relevant time periods discussed herein.

8. 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.

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

10. Accordingly, the Plaintiffs are victims of a calculated profit driven market scheme devised by, Defendant a large multinational pharmaceutical drug manufacturer, whose interests to secure profits upon sale of its drug products superseded consideration for the life changing physical consequences its products can impact upon consumers. Though having already paid billions of dollars in settlements for analogous impropriety conduct that is the subject of this lawsuit in the recent past, this recidivist Defendant has once again violated regulatory mandates and deliberately circumvented necessary and reasonable precautions at the expense of safety and harm for the Plaintiffs, purely for pecuniary gain.

JURISDICTION AND VENUE

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

12. 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.

13. 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 has advertised, promoted, supplied, and sold pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public in New Jersey deriving substantial revenue in this district.

PARTIES

14. Plaintiffs Saro and Lee Mandoyan are citizens of the United States. Plaintiffs are the natural father, mother and guardians of B.M. Plaintiffs reside in Bergen County, New Jersey

15. 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.

16. 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.

17. At all relevant times, GSK conducted business in the State of New Jersey and have derived substantial revenue from products, including Zofran, sold in New Jersey.

FACTUAL ALLEGATIONS

LEE MANDOYAN'S PREGNANCY

18. Plaintiffs Saro and Lee Mandoyan are the natural birth parents of B.M.

19. As a measure of precaution, six months prior to being pregnant, Plaintiff Lee Mandoyan undertook antepartum testing, blood work and other physical testing to assess her physical capacity to have a child. All physical tests Lee Mandoyan undertook revealed normal and healthy results.

20. As an added precaution Plaintiff Lee Mandoyan began taking prenatal vitamins six months prior to her pregnancy

21. Plaintiff Lee Mandoyan, does not drink caffeine, is a nonsmoker, and has not ingested alcohol of any kind in over 15 years.

22. Plaintiff Lee Mandoyan, three weeks into her pregnancy was admitted to the hospital for dehydration and nausea. She was diagnosed with hyperemesis gravidarum. As a result, Plaintiff Lee Mandoyan experienced episodic periods of nausea and dehydration throughout her pregnancy.

23. To mitigate her nausea, Plaintiff Lee Mandoyan was prescribed Zofran as early as five weeks into her pregnancy. When admitted into the hospital Plaintiff Lee Mandoyan was administered Zofran intravenously.

24. After Plaintiff Lee Mandoyan was discharged, she was prescribed Zofran by way ingestible 4 mg tablets tablet to take daily every six hours.

25. When Plaintiff Lee Mandoyan's nausea persisted eight weeks into her pregnancy, her Doctor increased her dosage amount from 4 to 8 mg per dosage. Plaintiff Lee Mandoyan maintained the 8mg dosage level of Zofran throughout the remainder of her pregnancy

26. Also during her first trimester Plaintiff Lee was also prescribed a Zofran Pump for approximately four days. During such time, Plaintiff Lee Mandoyan received Zofran by way of premixed injection through her stomach. The Zofran pump discharged Zofran into Plaintiff Lee Mandoyan cyclically every 4 hours.

27. After using the Zofran pump for four days, Plaintiff Lee Mandoyan was prescribed Zofran in a dissolvable pill format daily to take every 4 hours.

28. At the doctor's prescription, Plaintiff Lee Mandoyan would continue to take Zofran dissolvable pills every four hours at 8 mg dosage level for the remainder of her pregnancy.

29. Plaintiff Lee Mandoyan never took any other anti-nausea drug.

30. Plaintiff Lee Mandoyan was not prescribed any other drug or medication during her pregnancy besides Advair, which she took at her regular dosage level for two weeks because she did not experience any asthmatic symptoms during her pregnancy

31. Plaintiff Lee Mandoyan regularly took prenatal vitamins as prescribed throughout the course of her pregnancy.

32. Plaintiff Lee Mandoyan carried B.M. for 40 weeks and one 1 day until birth.

B.M.'S BIRTH

33. B.M. was born on September 24, 2011 at Englewood Hospital, weighing 7.5 pounds and measuring 19 and 3 quarters inches in length.

34. Consistent with the March 15, 2011 diagnosis, B.M. was born with a congenital birth defect known as clubfoot. Clubfoot also called, congenital *talipes equinovarus*, is a congenital deformity involving one foot or both of a child. At birth B.M.'s feet appeared to have been rotated internally at the ankle.

35. Nine days in his birth B.M.'s physicians gently manipulated tissues forming ligaments, joint capsules and tendons amid B.M.'s feet, bended, straightened and ultimately inserted each of his feet into a plaster cast that run from the B.M.'s toes to mid thighs. The plaster casting was used to isolate B.M.'s legs, knees and feet so that his feet could be could be properly positioned to obtain the degree of correction.

36. After a week's time, B.M's medical physicians would cut and remove the plaster cast to again examine B.M.'s feet, legs, and again gently manipulate tissues forming ligaments, joint capsules and tendons amid his feet and then recreated another plaster cast to isolate his feet, knees and legs in a position to obtain the degree of correction needed to walk and use his feet normally. This process of casting, cutting, and recasting transpired on a cyclical weekly basis for the first two months into B.M.'s birth.

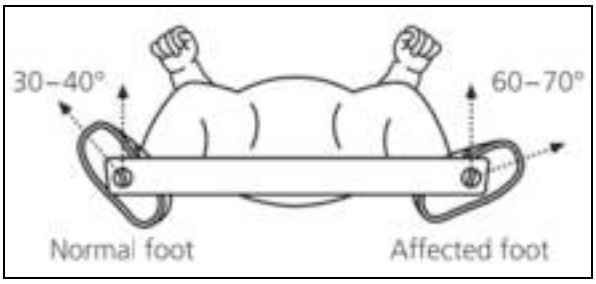
37. After two months, B.M was admitted into the hospital to receive a tenotomy. A tenotomy is a surgical act, which involves the literal cutting and slicing of a division of an Achilles tendon. B.M.'s physicians administered the procedure in the hopes of lengthening B.M. tendon and gradually reset his feet to their appropriate alignment.

38. After receiving the procedure, B.M.'s legs and feet were again placed in a plaster cast applied from his toes to mid thighs for several weeks in attempts to maintain the degree of correction maintained by the tenotomy in attempts to ensure that his displaced bones are gradually brought into the correct alignment.

39. Following the casting period B.M. endured during the tenotomy was prescribed a Mitchell shoe, sandal-type footwear that consists of a molded plastic footplate and three soft leather straps. The Mitchell shoe is an-open-toed high-top shoes with a well-molded heel. Between the Mitchell shoes are an attached metallic bar runs the length between B.M.'s shoulders.

40. With respect to the metallic bar than runs the length between B.M.'s Mitchell shoes, Plaintiffs used both the Ponsetti and Dobbs bar both bars, though varying in flexibility were used to hold B.M.'s feet at 45 degrees angle with along with dorsiflexion in attempts to hold B.M.'s fee to his correct level of abduction.

41. Sketch of foot positioning by means of a Mitchell Shoe and Ponseti abduction brace.



42. B.M. was required to wear the Mitchell Shoes with the Ponsetti/Dobbs bar in order to suspend movement in his feet at fixed 45-degree angle for 23 hours a day for six months.

43. After the first six months of wearing the Mitchell shoes and Ponseti/Dobbs bar, B.M. would continue wearing the bar for an additional six months for 18 hours a day.

44. After the second six month period B.M. was required to wear the Mitchel Shoe and Dobbs Bar, B.M. would continue wearing the same for another 6 months, at 12 hours a day.

45. All throughout the course of infancy when B.M. wore the Mitchell Shoes and Ponsetti or Dobbs Bar, the metallic bar often clashed and bumped against the bars of his baby crib at night precluding B.M.'s ability to sleep normally.

46. Consequently Plaintiff's have had to share a bed with B.M. since the early days of his infancy.

47. Additionally, B.M. suffered pressure blisters and sores against his feet while wearing the Mitchell Shoes.

48. For periods outside of wearing the orthopedic devices, Plaintiffs Saro and Lee Mandoyan would spend 45 minutes to an hour per day conducting physiotherapy on B.M.'s feet and legs stretching and manipulating B.M.'s Achilles tendons and calf muscles by hand or by use of a Dorsi Ramp to further abduct the muscles and ligaments and tendons in B.M.'s feet to gradually adjust to the appropriate degree and level of correction.

49. At all material times of casting and recasting, and wearing the Mitchell shoes and Ponsetti and Dobbs Bar, B.M. could not learn to walk and was reduced to crawling with plaster casts and subsequent orthopedic devices fastened to his feet.

50. As a consequence thereof, B.M. had to learn to urinate sitting down while wearing the orthopedic devices

51. Plaintiffs Lee and Saro Mandoyan incurred great hardships selecting schools for B.M.. Teachers were unable to pick him up to change him. B.M's natural socialization with other children was impeded on account of his immobility.

52. To date B.M. continues to wear the Mitchell Boots & Dobbs bar when he sleeps. However recent examination of B.M.'s feet has shown that his clubfoot condition has regressed requiring more surgery and possible a tendon transplant.

53. The tendon transplant possessing a 20% fail rate, will require B.M. to remain in a plaster cast for another 6 months. The effects of his clubfoot will last him a lifetime.

54. Plaintiffs Saro and Lee Mandoyan have no genetic history of any member of their families being born with congenital disorder.

PERTINENT BACKGROUND ON ZOFRAN

55. 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 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.)

56. The medical term for nausea and vomiting is emesis, and drugs that prevent or treat nausea and vomiting.

57. 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 types 3 (5-HT3).

58. Although 5-hydroxytryptamine (5HT) occurs in most tissues of the human body, Zofran is believed to block the effect of serotonin at the 5HT3 receptors located along vagal afferents in the gastrointestinal tract and at the receptors located in the area postrema of the central nervous system (the structure in the brain that controls vomiting). Put differently, Zofran antagonizes, or inhibits, the body's serotonin activity, which triggers nausea and vomiting.

59. 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).

60. 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).

61. 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)

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

63. 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.

64. A team of the FDA's physicians, statisticians, chemists, pharmacologists, microbiologists and other scientists would then have an opportunity to: (a) review the company's data and evidence supporting its request for approval to market the drug; and (b) determine whether to approve the company's request to market the drug in the manner requested. Without

first obtaining approval to market a drug for the treatment of pregnant women, a pharmaceutical company may not legally market its drug for that purpose.

65. 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.

66. 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.

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

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

Preclinical Studies

68. 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.

69. 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.

70. 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. The sponsor, GSK, to show no harm to the fetus, stated these preclinical teratogenicity studies in rats and rabbits but the data also revealed clinical signs of toxicity, premature births, intrauterine fetal deaths, and impairment of ossification (incomplete bone growth).

71. 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 effect

72. 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 groups versus

lower- dose groups. The study also reported maternal weight loss in the exposed groups. Developmental retardation in offspring and fetuses were noted – namely, areas of the parietal (body cavity) were not fully ossified, and the hyoid (neck) failed to ossify completely.

73. Study No. R10590 Oral Segment II teratological study of rats. Four 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 groups. Body weight, gestational duration and fetal examinations were reported as normal, but "slight retardation in skeletal ossification was noted in the offspring.

74. 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."

75. 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 to GSK of Zofran-Related Birth Defects to GSK

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

77. 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.

78. 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.

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

80. 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.

81. 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

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

83. 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").

84. 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.

85. 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.

87. 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.

88. 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.

89. 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

90. 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).

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

92. 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*.

93. 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).

94. 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. Mandoyan and her prescribing healthcare provider.

95. 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.

96. 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.

97. 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."

98. 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.

99. 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.

100. 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."

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

102. 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.

103. 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).

104. 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).

105. 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.

106. 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."

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

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

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

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

110. 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. 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.

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

112. 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.)

113. 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.

114. 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."**

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

116. 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).

117. 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.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

118. 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.

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

120. GSK failed to exercise ordinary care and failed to comply with existing standards of care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished

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

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

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

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

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

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

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

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

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

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

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

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

k. Failing to provide adequate instructions regarding birth defects including congenital clubfoot;

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

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

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

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

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

125. Had Plaintiffs' son B.M. not taken Zofran, her baby would not have suffered those injuries and damages as described herein with particularity.

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

127. Plaintiffs' son B.M. also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

128. As a result of the foregoing acts and omissions, Plaintiff requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that their child will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

SECOND CAUSE OF ACTION
(NEGLIGENCE PER SE)

130. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

132. GSK failed to exercise ordinary care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

133. GSK, its agents, servants, and/or employees, failed to exercise ordinary care and violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.128, in particular.

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

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

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

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

138. Had Plaintiffs son B.M. not taken Zofran, their baby would not have suffered those injuries and damages as described herein.

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

140. Plaintiffs' son B.M. also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

141. As a result of the foregoing acts and omissions, Plaintiffs require and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs informed and believe and further allege that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

THIRD CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

143. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

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

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

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

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

149. Plaintiffs have also sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

150. As a result of the foregoing acts and omissions, Plaintiffs require and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

FOURTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

152. 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.

153. GSK falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiffs their providers, that:

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

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

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

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

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

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

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

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

158. In reliance upon said representations, Plaintiffs' prescriber was induced to prescribe Zofran to her, and Plaintiff Lee Mandoyan was induced to and did use Zofran to treat pregnancy-related nausea.

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

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

161. As a result of the foregoing acts and omissions, B.M. 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, monitoring and/or medications.

162. Plaintiffs sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

163. As a result of the foregoing acts and omissions, Plaintiffs require and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that their child will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

FIFTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

165. 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.

166. In representations to Plaintiffs' healthcare providers, expectant mothers including Plaintiffs and the FDA, GSK fraudulently concealed and intentionally omitted the following material facts:

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

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

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

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

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

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

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

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

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

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

170. As a result of the foregoing acts and omissions, B.M. 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, monitoring and/or medications.

171. Plaintiffs have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

172. As a result of the foregoing acts and omissions, Plaintiffs require and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that their child will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

SIXTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

174. 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.

175. GSK falsely and negligently represented to the medical community and expectant mothers, including Plaintiff and her providers, that:

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

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

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

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

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

177. As a result of the foregoing acts and omissions, B.M. 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, monitoring and/or medications.

178. As a result of the foregoing acts and omissions, B.M. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that B.M. will in the future be required to obtain further medical and/or hospital care, attention, and services.

179. Plaintiffs have also sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

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

SEVENTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

181. 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.

182. Defendants expressly warranted that:

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

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

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

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

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

184. Plaintiffs their healthcare providers did rely on the express warranties of the GSK herein.

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

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

187. As a result of the foregoing acts and omissions, B.M. was caused to suffer serious and dangerous side effects including, life-threatening birth defects, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

188. Plaintiffs have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

189. As a result of the foregoing acts and omissions, B.M. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that B.M. will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

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

191. 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.

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

193. GSK's product was not fit for the ordinary purpose for which such goods were used. It was defective in design and its failure to provide adequate warnings and instructions, and

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

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

NINTH CAUSE OF ACTION
(FRAUD)

195. 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.

196. At all relevant and material times, Defendants expressly and/or impliedly warranted that Zofran was safe, of merchantable quality and fit for use.

197. Defendants' superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and dangers of Zofran, and its intentional dissemination of promotional and marketing information about Zofran for the purpose of maximizing sales, each gave rise to the affirmative duty to meaningfully disclose all material information about the risks and harms associated with the products.

198. At all times herein mentioned, Defandants fraudulently represented to Plaintiffs, physicians, and other persons and professionals whom Defendants knew would justifiably rely on Defendants' representations, as well as the public at large, that Zofran were safe and effective for use by Plaintiffs.

199. Defendants intentionally failed to disclose to Plaintiff and others important safety, risk, adverse event and injury information, including but not limited to the increased risk of

congenital clubfoot. Defendants suppressed material facts about the products while having a duty to disclose such information, which duty arose, in part, from the Defendants designing, manufacturing, marketing, advertising, distributing and selling such products.

200. Defendants' false representations were fraudulently made, with the intent or purpose that Plaintiff and healthcare providers involved in providing treatment to Plaintiff would justifiably rely upon them, leading to the use of Zofran.

201. Defendants' deliberate misrepresentations and/or concealment, suppression, and omission of material facts as alleged herein, include, but are not limited to:

a. Making false and misleading claims regarding the known risks of Zofran and suppressing, failing to disclose and mischaracterizing the known risks of Zofran, including but not limited to congenital clubfoot.

b. Making false and misleading written and oral statements that Zofran are more effective than other anti-nausea medications and/or omitting material information showing that Zofran are no more effective than other available anti-nausea medications.

c. Misrepresenting or failing to timely and fully disclose the true results of clinical test and studies related to Zofran.

d. Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of using Zofran which would disclose the nature and extent of the harmful side effects of Zofran.

e. Making false and misleading claims that adequate clinical testing had been don and/or failing to disclose that adequate and/or generally accepted standards for pre-clinical and clinical testing had not been followed; and

f. Making false and misleading representations concerning the safety, efficacy and benefits of Zofran without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.

202. Defendants' willfully, wantonly, and recklessly disregarded their duty to provide truthful representations regarding the safety and risks of Zofran.

203. Defendants made the misrepresentations with the intent that doctors and patients, including Plaintiffs, rely upon them.

204. Defendants' misrepresentations were made with the intent of defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and encourage the sale of Zofran.

205. Defendants' fraudulent representations evidence their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiffs.

206. Defendants omitted, misrepresented, suppressed, and concealed material facts concerning the dangers and risks of injuries associated with the use of Zofran, including the increase risk of serious injury as well as the fact that the product was unreasonably dangerous.

207. Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Zofran in order to increase sales.

208. Plaintiffs' and that treating medical community did not know that Defendants' representations were false and or misleading and justifiably relied on them.

209. Defendants had sole access to material facts concerning the dangers and unreasonable risks of Zofran.

210. The intentional concealment of information by Defendants about the substantial risks of serious injury associated with Zofran was known by defendants to be wrongful.

211. Had Defendants not fraudulent concealed such information, Plaintiff would not have used Zofran.

212. Had Plaintiffs been aware of the increased risks of serious injury associated with the Zofran, plaintiff would not have used Zofran.

213. As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment of facts, upon which plaintiff reasonably relied, Plaintiffs suffered injuries and damages.

214. As a direct a and proximate consequence of Defendants negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts described herein, Plaintiff sustained injuries and damages.

TENTH CAUSE OF ACTION
(VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT BY UNCONCIONABLE COMMERCIAL PRACTICES, DECEPTION, FRAUD, FALSE PRETENSES, FALSE PROMISES, MISREPRESENTATIONS)

215. 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.

216. The New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-2, ("CFA") prohibits:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of merchandise. . .

217. "Merchandise" includes "any…services or anything offered, directly or indirectly to the public for sale. *Id*. § 56:8-1(c).

218. Zofran is "merchandise" within the meaning of the CFA.

219. "Person" includes "any natural person…partnership, corporation, company,…business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestius que trustent thereof." *Id* § 56:8-1(c).

220. Defendants are "persons" under the CFA.

221. As described herein, Defendants' unconscionable commercial practices, deception, fraud, false pretenses, false promises, and misrepresentations to Plaintiffs' include, *inter alia*, the following:

a. Making false and misleading claims regarding the known risks of Zofran and suppressing, failing to disclose and mischaracterizing the known risks of Zofran, including but not limited to congenital clubfoot.

b. Making false and misleading written and oral statements that Zofran are more effective than other anti-nausea medications and/or omitting material information showing that Zofran are no more effective than other available anti-nausea medications.

c. Misrepresenting or failing to timely and fully disclose the true results of clinical test and studies related to Zofran.

d. Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of using Zofran which would disclose the nature and extent of the harmful side effects of Zofran.

e. Making false and misleading claims that adequate clinical testing had been don and/or failing to disclose that adequate and/or generally accepted standards for pre-clinical and clinical testing had not been followed; and

f. Making false and misleading representations concerning the safety, efficacy and benefits of Zofran without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.

222. Defendant, in the course of marketing, promoting, selling, and distributing prescription drugs in New Jersey, has engaged in the advertisement or sale of merchandise through unconscionable commercial practices and deception in violation of the CFA, specifically by making written and oral representations about Zofran when Defendant knew the written and oral representations were not true.

223. Defendant consciously omitted to disclose material facts to Plaintiffs, other consumers, and the medical community with regard to Zofran in its advertising and marketing of the product.

224. Defendant's unconscionable conduct described herein included the omission and concealment regarding Zofran in the product's advertising and marketing.

225. Defendant intended that Plaintiffs, other consumers, and the medical community rely on Defendant's acts and omissions so that Plaintiff, other consumers, and the medical community would purchase Zofran.

226. Had Defendant disclosed all material information regarding Zofran, Plaintiffs would not have used Zofran.

227. The acts, omissions and practices of Defendant detailed herein proximately caused Plaintiff to suffer an ascertainable loss in the form of, inter alia, medical bills for the treatment of clubfoot that they otherwise would not have, and they are entitled to recover such damages, together with appropriate penalties, including treble damages, attorneys' fees and costs of suit.

228. As a result, Plaintiff has suffered an ascertainable loss of moneys and pursuant to N.J.SA. § 56:8-19 is entitled to threefold damages.

229. N.J.S.A. § 56:8-19 further provides that "[i]n all actions under this section, including those brought by the Attorney General, the court shall also award reasonable attorneys' fees, filing fees and reasonable costs of suit."

ELEVENTH CAUSE OF ACTION
(FAILURE TO WARN)

230. 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.

231. Zofran are unreasonably dangerous, even when used in a foreseeable manner as designed and intended by Defendants.

232. Defendants failed to warn and/or adequately warn Plaintiffs, consumers, Physicians, and healthcare professionals of the increased health risks associated with using Zofran.

233. Plaintiffs did not have the same knowledge as Defendants and no adequate warning was communicated to them.

a. Failed to include warnings and/or adequate warnings of the increased risk of serious injury, including birth defects such as congenital clubfoot when Zofran was taken by pregnant women, and other adverse effects;

b. Failed to provide adequate and proper instructions regarding the proper use of Zofran to prevent birth defects such as congenital clubfoot when Zofran is taken by pregnant women, and other adverse effects;

c. Failed to inform Plaintiffs that Zofran it not been adequately tested to determine the safety and risks associated with using the product;

d. Failed to warn that the risks associated with the use of Zofran exceeded the risks of other available forms of treatment for Plaintiffs' condition;

e. Failed to report adverse events to the FDA associated with the ingestion and/or injection of Zofran.

234. Defendants and each of them had a duty to warn the FDA, the medical community, Plaintiff and Plaintiffs' physicians a about the increase of injury but failed to do so.

235. Defendants, individually and collectively, had a duty not to engage in illegal off-label promotion of Zofran but failed to do so.

236. As a direct and proximate result of the actions and inactions of Defendants as set forth above Plaintiffs sustained injuries and damages.

DEMAND FOR JURY TRIAL

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against GSK on each of the above-referenced claims and Causes of Action and as follows:

a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

b) For medical, incidental and hospital expenses according to proof;

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

d) For full refund of all purchase costs of Zofran;

e) For consequential damages in excess of the jurisdictional minimum of this Court;

f) For compensatory damages in excess of the jurisdictional minimum of this Court;

g) For treble damages;

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

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

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

Dated: June 26, 2015

HARBATKIN & LEVASSEUR, PA

/s/ Audwin F. Levasseur
AUDWIN F. LEVASSEUR, ESQ.
Attorneys for Plaintiffs