IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: ZOFRAN (ONDANSETRON) PRODUCTS LIABILITY LITIGATION	**MDL No. 1:15-md-2657-FDS**
This Document Relates To: All Actions	
Plaintiffs,	**MASTER LONG FORM COMPLAINT AND JURY DEMAND – BRAND ZOFRAN® USE**
v.	
GLAXOSMITHKLINE LLC, NOVARTIS PHARMACEUTICALS CORPORATION	
Defendants.	

PLAINTIFFS' MASTER LONG FORM COMPLAINT AND JURY DEMAND
BRAND ZOFRAN® USE

COME NOW, MDL Plaintiffs through counsel and submit this Brand Master Long Form Complaint ("Brand Master Complaint"). This Brand Master Complaint sets forth potential claims of Plaintiffs who were injured as a result of prenatal exposure to branded Zofran® against Defendants GlaxoSmithKline LLC d/b/a GlaxoSmithKline and, as to claims arising after March 23, 2015, against Novartis Pharmaceuticals Corporation (collectively, "Defendants") for damages and such other relief deemed just and proper. Plaintiffs plead all Counts of this Brand Master Complaint in the broadest sense, pursuant to all laws that may apply under controlling choice of law principles, including the laws of the individual each Plaintiff's home states.[1]

[1] A separate Master Long Form Complaint will be filed to set forth potential claims of Plaintiffs who ingested generic ondansetron and/or ondansetron hydrochloride (hereinafter, "ondansetron"), the generic versions of Zofran. Plaintiffs who ingested the authorized generic ondansetron manufactured and/or sold by GSK and Sandoz, Inc. in 2007 and 2008, however, may adopt claims from this Brand Master Complaint.

This Brand Master Complaint is intended to serve the administrative functions of efficiency and economy by presenting certain common claims and common questions of fact and law that generally pertain to the Plaintiffs adopting this Complaint. This Master Long Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court. It is anticipated that individual Plaintiffs will adopt this Brand Master Complaint and selected causes of action herein through the use of a separate Brand Short Form Complaint. Any separate facts and additional legal claims of individual Plaintiffs may be set forth as necessary in the Short Form Complaint filed by the respective Plaintiffs. This Brand Master Complaint does not constitute a waiver or dismissal of any claims asserted in those individual actions, and no Plaintiff relinquishes the right to amend his or her individual claims to include additional claims as discovery and trials proceed.

I. THE PARTIES

A. PLAINTIFFS

1. This Brand Master Complaint is filed for and on behalf of all individual Plaintiffs, including parents and natural guardians individually and on behalf of their minor children and, if applicable, the legal representatives of the estates of those who were born with birth defects or had a child born with a birth defect after prenatal exposure to the prescription drug Zofran® (hereafter, "Zofran"). As a direct and proximate cause of these exposures to Zofran, Plaintiffs suffered severe injuries and/or death and damages therefrom.

B. DEFENDANTS

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

3. At all relevant times, GSK conducted business throughout the United States. GSK has derived substantial revenue from pharmaceutical sales throughout the United States, including from Zofran and from generic ondansetron sales through its authorized generic distributor, Sandoz, Inc. GSK manufactured and/or sold both branded Zofran and generic ondansetron distributed by Sandoz, Inc. in 2007 and 2008.

4. GSK is a subsidiary of GlaxoSmithKline plc and 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 (which also was a division of Glaxo Wellcome Inc.), 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.

5. In 1995, Glaxo Inc. merged with another company to form Glaxo Wellcome Inc., which later merged with SmithKline Beecham to form SmithKline Beecham Corporation d/b/a GlaxoSmithKline. As a result of these mergers, Glaxo, Inc. and Glaxo Wellcome Inc. ceased to exist as legal entities. In 2009, SmithKline Beecham Corporation converted into GlaxoSmithKline LLC, or GSK. 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, labeling and/or distribution of Zofran and/or post-market vigilance regarding same.

6. Until March 23, 2015, GSK was the sponsor of the NDAs for Zofran, and the responsible party for, among other things, Zofran testing, marketing, labeling and post-market vigilance.

7. Effective March 23, 2015, Novartis AG, a Switzerland company, entered into an agreement to acquire GlaxoSmithKline PLC's oncology business, including the right to sell Zofran products in the United States. On or about March 23, 2015, Novartis Pharmaceuticals Corporation ("Novartis"), a United States corporation and subsidiary of Novartis AG, became the NDA holder for Zofran. On or about March 23, 2015, Novartis assumed responsibility for maintaining the content of Zofran's label and labeling in the United States, including warnings and precautions attendant to its use.

8. At all relevant times until GSK's sale of its Zofran business to Novartis, GSK designed, researched, manufactured, tested, packaged, labeled, advertised, promoted, marketed, sold and distributed Zofran. After the sale of GSK's oncology business to Novartis, GSK continued to manufacture Zofran products for sale in the United States by Novartis, and Novartis became involved in the research, manufacture, testing, packaging, labeling, advertising, promoting, marketing, and selling of Zofran in the United States.

9. Novartis is a Delaware corporation with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936.

10. At all relevant times, Novartis conducted business throughout the United States. Novartis has derived substantial revenue from pharmaceutical sales throughout the United States, including Zofran.

11. The term Novartis used herein refers to Novartis Pharmaceuticals Corporation and other Novartis predecessors and/or affiliates that discovery reveals were involved in the testing, development, manufacture, marketing, sale, labeling and/or distribution of Zofran.

12. In connection with its acquisition of Zofran from GSK, Novartis gained knowledge of the false and misleading promotion of Zofran for treating pregnancy-related

nausea, sometimes referred to as morning sickness, and of the risks of prenatal exposure to Zofran. Novartis had a duty and continues to have a duty to warn adequately and to correct GSK's misrepresentations and has failed to do so.

II. JURISDICTION AND VENUE

13. 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 and Novartis are citizens of states other than the state in which Plaintiffs are citizens.

14. Pursuant to the Transfer Order of the Judicial Panel on Multidistrict Litigation, *In re Zofran (Ondansetron) Products Liab. Litig.*, No. MDL 2657, 2015 WL 6045619, at *1 (Oct. 13, 2015), venue in actions such as this one sharing common questions with the initially transferred actions is proper in this district for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407.

15. At all times herein mentioned, GSK and Novartis conducted, and continue to conduct, a substantial amount of business in this judicial district. GSK and Novartis have maintained offices in this district, and GSK and Novartis are registered to conduct business in this district, each having a Resident Agent located in Boston, Massachusetts. GSK and Novartis engaged in interstate commerce when they advertised, promoted, supplied, and sold pharmaceutical products, including Zofran, deriving substantial revenue in this district. Although the plans to misleadingly market Zofran for pregnancy were devised outside this district, they were executed nationwide.

III. BACKGROUND AND NATURE OF THE CASE

16. Zofran is a prescription drug indicated only for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting, or post-operative nausea and/or vomiting.

17. Drugs that prevent or treat such nausea and vomiting are called anti-emetics. Zofran is part of a class of anti-emetics referred to as selective serotonin 5-HT3 receptor antagonists.

18. The active ingredient in Zofran is ondansetron or ondansetron hydrochloride, which are referred to as selective antagonists at the 5-hydroxytryptamine receptor type 3 (5-HT3). At all relevant times, Defendants have not publicly characterized the mechanism of action of Zofran or its active ingredient in the human body.

19. Serotonin, or 5-hydroxytryptamine (5-HT), is a neurotransmitter found in most tissues of the human body. Serotonin signaling in the human body triggers nausea and vomiting. Zofran is believed to inhibit the body's serotonin signaling, thereby alleviating symptoms of nausea and vomiting.

20. Serotonin signaling also regulates developmental processes that are critical to normal embryonic development. Inhibiting serotonin signaling during embryonic development increases the risk of birth defects. Defendants have been aware of these facts at all relevant times, but they have failed to inform healthcare providers, their patients or the public of this increased risk.

21. Among patients who ingested Zofran, the drug has caused sometimes fatal cardiac arrhythmias such as QT prolongation and Torsade de Pointes; serotonin syndrome; disruption of signaling pathways through neurotransmitters other than serotonin. Defendants have been aware of these facts at all relevant times, but they have failed to inform healthcare providers, their patients, or the public of the impact of these potentially life-threatening conditions on the developing embryo and fetus.

22. The extent and rate of ondansetron's absorption is greater in women than in men. Zofran's slower clearance in women, and greater volume of distribution and bioavailability in women cause it to affect women differently than men. Defendants have at all relevant times disregarded these gender-related differences by marketing the drug to treat pregnancy-related nausea and vomiting and/or failing to correct misrepresentations about the safety and efficacy of the drug when prescribed for that purpose. Defendants have failed to characterize ondansetron's pharmacokinetic parameters in pregnant women, embryos, or fetuses, or if they have, they have not disclosed those parameters to healthcare providers, patients or the public.

23. In 1991, Zofran became the first 5-HT3 receptor antagonist approved for marketing in the United States. Other drugs in the class of 5-HT3 receptor antagonist include Kytril® (granisetron) (FDA-approved 1994), Anzemet® (dolasetron) (FDA-approved 1997), and Aloxi® (palonosetron) (FDA-approved 2003).

24. Zofran is available as an injection (2 mg/mL), a premixed injection (4 mg/50 ml), oral tablet (4 mg, 8 mg and 24 mg), orally disintegrating tablet (4 mg and 8 mg), and an oral solution (4 mg/5 mL).

25. More specifically, GSK obtained FDA approval for the following forms 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).

26. Defendants have never applied for FDA approval of Zofran for the treatment of pregnancy-related nausea or vomiting. Neither the safety nor efficacy of Zofran for the treatment of pregnancy-related nausea or vomiting has been established.

GSK Fraudulently Promoted Zofran and Created a New Market for Zofran.

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

28. With more than six million annual pregnancies in the United States since 1991 and an estimated 70-85% incidence of pregnancy-related nausea, GSK had an extremely lucrative business opportunity to create a new market for 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 children throughout the United States.

29. At least as early as January 1997, 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 healthcare practitioners and consumers as a safe and effective treatment for pregnancy-related nausea and vomiting.

30. In support of its misleading marketing efforts, at least as early as January 1997, GSK offered and paid substantial remuneration to healthcare providers and "thought leaders" to induce them to promote and prescribe Zofran to treat morning sickness.

31. In 1998, GSK sought additional patent protection for Zofran. In support of its application, GSK asserted that "Ondansetron is useful in the treatment of emesis however induced. For example, emesis may be induced by . . . pregnancy."

32. When Zofran was first marketed—for treatment of cancer patients—GSK's Oncology Division sales force had primary responsibility for marketing and promoting the drug. Beginning in at least January 1997, GSK began expanding 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 promotional strategy that would enable GSK to leverage its Consumer Health Care Division's established relationships with obstetricians and gynecologists. Thus, GSK's Oncology Division began partnering with GSK's Consumer Health Care Division to promote Zofran.

33. Specifically, in or about 2001, GSK's Oncology Division finalized a co-marketing agreement with GSK's Consumer Health Care division under which sales representatives from GSK's Consumer Health Care division marketed Zofran to obstetricians and gynecologists. When they entered this agreement, GSK's Consumer Health Care sales force already had established relationships with, and routinely called on, obstetricians and gynecologists and other providers to promote and provide samples of another GSK product, Tums, for the treatment and prevention of heartburn during pregnancy. GSK's established network for promoting Tums for use in pregnancy afforded it an additional conduit for promoting Zofran for use in pregnancy.

34. GSK's primary purpose in undertaking this co-marketing arrangement was to promote Zofran to obstetricians and gynecologists during GSK's Consumer Health Care 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 morning sickness in pregnancy, thereby increasing sales and profits.

35. 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 the representative 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 the compensation and incentives.

36. 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 most frequently prescribed drug for treating morning sickness in the United States. In 2002, sales of Zofran in the United States reportedly totaled $1.1 billion.

37. GSK's promotion of Zofran for use in pregnancy eventually led to a federal governmental investigation. On July 2, 2012 the U.S. Department of Justice announced that GSK "[a]greed 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.

38. Part of GSK's civil liability to the government included payments arising from claims that GSK: (a) promoted and disseminated false representations about the safety and efficacy of Zofran concerning pregnancy-related nausea; and (b) paid and offered to pay illegal remuneration to healthcare professionals to induce them to promote and prescribe Zofran for this purpose.

39. GSK's 2012 civil settlement with the United States covered false and misleading promotional conduct that was part of an overarching plan to maximize highly profitable Zofran sales without due regard to protecting 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 strategy 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 as described in this paragraph continued until the Department of Justice began investigating these marketing methods in the early 2000s, but the effect of the promotional campaign was to create a new market for Zofran that was founded on false and misleading promotion.

Defendants Knew Zofran Presents an Unreasonable Risk of Birth Defects Among Children Exposed Prenatally.

40. Since before Zofran entered the U.S. market, GSK has known that serotonin also regulates developmental processes that are critical to proper embryonic development. Impeding serotonin signaling during embryonic development can increase the risk of developmental insult. GSK has likewise known that, when Zofran is taken alone or in combination with other drugs, its established side effects in adults can also occur in embryos and fetuses, leading to birth defects. Novartis has been aware of these facts since before it began selling Zofran.

41. GSK's marketing of Zofran for treating pregnancy-related nausea and its knowledge of Zofran's widespread use in pregnancy gave rise to a need for Defendants to closely monitor the signals of birth defect risks in the post-market setting. Defendants failed to do so, or if they did, they concealed the results of their evaluations, despite the emergence of safety concerns from the medical community after GSK began promoting Zofran for the treatment of pregnancy-related nausea.

42. At all relevant times, Defendants were on actual and/or constructive notice of (a) the mechanisms by which *in utero* ondansetron exposure can induce birth defects; (b) the preclinical studies demonstrating signals of teratogenic effects; (c) studies demonstrating human embryonic and fetal exposure during prenatal Zofran ingestion; (d) evidence establishing that Zofran's side effects in adults can also occur in embryo and fetuses; (e) widespread use of Zofran by pregnant women during the periods when the embryos and fetuses are highly susceptible to developmental insult by a pharmaceutical agent; (f) adverse event reports of birth defects in humans; and (g) studies reporting an increased risk of birth defects in human populations. In short, Defendants were on notice that the weight of available evidence established that Zofran exposure during pregnancy can cause birth defects.

43. By way of example, since at least the 1980s, when GSK received the results of preclinical studies, GSK has known that Zofran ingested during pregnancy in mammals crosses the placental barrier, exposing 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 these studies revealed that the rat and rabbit fetuses were exposed prenatally to Zofran during pregnancy.

44. Maternally ingested Zofran crosses the placenta in humans and exposes the developing embryo or fetus during pregnancy. The placental transfer of Zofran during human

pregnancy has been independently confirmed and detected in every sample of fetal tissue taken in a published study involving 41 pregnant patients.

45. Animal studies conducted as early as the 1980s by or on behalf of GSK in Japan and, upon information and belief, elsewhere outside of the U.S. have revealed clinical signs of toxicity, intrauterine fetal deaths, stillbirths, congenital heart defects, craniofacial defects, impairment of ossification (incomplete bone growth), and other malformations. GSK did not disclose any of these events to providers or consumers as teratogenic effects. GSK did not perform an adequate follow-up investigation of these events, or if it did, it has not disclosed the results.

46. From 1992 to the present, GSK has received reports of birth defects in children who were exposed to Zofran and ondansetron during pregnancy. GSK has received these reports directly and through studies published in medical literature.

Defendants Knew of Zofran's Widespread Use for Pregnancy-Related Nausea, and They Responded Recklessly to That Knowledge.

47. GSK's false and misleading marketing of Zofran as a safe and effective treatment for pregnancy-related nausea and vomiting created an unreasonable and foreseeable increased risk of birth defects in children exposed prenatally to Zofran. Upon conducting due diligence for its acquisition of the Zofran business, these risks became known and foreseeable to Novartis.

48. As early as 1997, GSK's marketing for pregnancy-related nausea and vomiting, payments to doctors for this use, and conspicuous increase in Zofran revenue demonstrate GSK's knowledge that physicians were, in fact, prescribing Zofran to treat nausea and vomiting in pregnancy. At the same time, GSK was aware that this Zofran use was associated with an increased risk for birth defects. Upon conducting due diligence for its acquisition of the Zofran business, these facts became known to Novartis.

49. Defendants had the ability to, without obtaining prior FDA approval, warn about the risks of ingesting Zofran for the treatment of morning sickness in pregnant women. Defendants negligently or fraudulently failed to do so, despite their knowledge that: (a) the safety of Zofran for use in human pregnancy has not been established, (b) there have been reports of birth defects associated with Zofran use during pregnancy, and (c) the weight of available evidence establishes an increased risk of birth defects in infants exposed to Zofran during pregnancy.

50. From 1993 to the present, despite mounting evidence of the birth defect risk, Zofran's prescribing information has included the same statement concerning its use 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."

51. This statement is false and misleading because animal studies conducted by or on behalf of GSK outside of the United States have in fact revealed evidence of teratogenic effects due to ondansetron, and because Defendants failed to conduct post-market studies that were properly designed to identify Zofran's true teratogenic risk. This statement is also misleading because it states that Zofran should be used during pregnancy if it is clearly needed, without limiting that representation to situations where it is clearly needed for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting, or post-operative nausea and/or vomiting. Finally, the above-quoted statement is negated by GSK's

affirmative marketing of Zofran as a safe and effective treatment for pregnancy-related nausea and vomiting and Defendants' failure to correct these misrepresentations.

52. GSK's Product Monographs for Zofran in Canada and Europe state "the safety of ondansetron for use in human pregnancy has not been established," and "the use of ondansetron in pregnancy is not recommended." Defendants failed to include even this basic language in their marketing materials and labeling in the United States, despite knowledge of the widespread use of the drug during pregnancy and despite the affirmative marketing of the drug for that purpose.

53. Defendants had a duty to inform healthcare providers and consumers in the United States about the lack of proven efficacy and risks of Zofran use during pregnancy. Defendants also had a duty not to make false or misleading representations or omissions concerning Zofran for the treatment of pregnancy-related nausea.

54. Had Plaintiffs' prescribers been informed about the risks and lack of proven efficacy of ondansetron use during pregnancy, they would not have prescribed Zofran or ondansetron to Plaintiffs for treatment of morning sickness, and Plaintiffs' families would not have suffered the harm that gave rise to this litigation.

55. GSK's misleading marketing of Zofran as a safe and effective treatment for pregnancy-related nausea and vomiting created an unreasonable increased risk of birth defects in children exposed prenatally to Zofran. In view of GSK's marketing of Zofran specifically for pregnancy-related nausea and vomiting, and Defendants' knowledge of widespread use of the drug for this purpose, the increased risk of birth defects was foreseeable to Defendants.

56. Defendants have at all relevant times failed to correct GSK's misrepresentations that Zofran is a safe and effective treatment for pregnancy-related nausea.

57. Defendants have at all relevant times failed to correct GSK's misrepresentations that Zofran is a safe and effective prophylactic treatment for the prevention of pregnancy-related nausea.

The Discovery Rule and Tolling of Limitations Periods Apply.

58. Prescribing physicians, healthcare providers and mothers-to-be, including Plaintiffs and their healthcare providers, neither knew, nor had reason to know at the time of their use of Zofran, of the existence of the aforementioned defects in the product. Ordinary consumers would not have recognized the potential risks or side effects, which Defendants concealed through promotion of Zofran as safe for treating pregnant women.

59. At all times herein mentioned, due to GSK's marketing of Zofran and Defendants' failures to correct the same, the drug was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants. Defendants knew or should have known that consumers, such as Plaintiffs and their minor children, would foreseeably suffer injury as a result of Defendants' failures to exercise reasonable care.

60. In summary, since at least 1992, Defendants have had mounting evidence showing that Zofran presents an increased risk of harm to babies who are exposed to the drug during pregnancy. Defendants have been aware that Zofran readily crosses human placental barriers during pregnancy. Defendants also have been aware that animal studies revealed deaths and birth defects. Since 1992, Defendants have received notice of reports of major birth defects associated with prenatal Zofran exposure. Defendants also have had actual and/or constructive knowledge of the scientific literature demonstrating Zofran's increased risk of birth defects.

61. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that Defendants' wrongful conduct caused the appreciable harm sustained by their

minor children. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful conduct that caused the injuries at an earlier time. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, the tortious nature of the conduct causing the injuries until a short time before filing of this action. Additionally, Plaintiffs were prevented from discovering this information sooner because: (1) GSK has misrepresented to the public and to the medical community that Zofran is safe for use in pregnancy; and (2) Defendants fraudulently concealed facts and information that could have led Plaintiffs to discover a potential cause of action.

62. The discovery rule tolls the running of the statute of limitations until Plaintiffs knew, or in the exercise of reasonable care and due diligence should have known, of facts indicating that Plaintiffs or their minor children had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury. In most states, limitations periods do not run against the claims of minor children.

FIRST CAUSE OF ACTION
NEGLIGENCE

63. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

64. Defendants had a duty to exercise reasonable care and comply with existing standards of care in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of Zofran, and post-market vigilance regarding same.

65. Defendants failed to exercise reasonable care and failed to comply with existing standards of care in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling, and/or distribution of Zofran and post-market vigilance regarding same. Defendants knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects.

66. Defendants, their agents, servants, and/or employees, failed to exercise reasonable care and failed to comply with existing standards of care in the following acts and/or omissions:

(a) Failing to adequately monitor and respond to the post-market pregnancy risks arising from use of Zofran to treat morning sickness;

(b) Failing to perform adequate testing to assess the safety and efficacy of the drug for treating pregnancy-related nausea;

(c) Failing to adequately and correctly warn the Plaintiffs, the public, and the medical and healthcare communities of the dangers of Zofran for pregnant women and their children;

(d) Failing to disclose their knowledge that Zofran ingested during pregnancy readily crosses a pregnant mother's placental barrier and exposes fetuses to substantial concentrations of Zofran for longer durations than the mother's exposure;

(e) Failing to disclose their knowledge that Zofran has been shown to inhibit the human embryo's serotonin activity, and that such serotonin activity regulates developmental processes that are essential to normal embryonic development;

(f) Failing to disclose their knowledge that Zofran's established side effects in adults can also occur in embryos and fetuses, leading to birth defects;

(g) Failing to disclose their knowledge that Zofran's established side effects in adults can also occur in embryos and fetuses in combination with other drugs that have the same side effects, leading to birth defects;

(h) Failing to disclose reports of birth defects associated with Zofran to providers and consumers;

(i) As to GSK, promoting the use of Zofran and providing kickbacks (payments and offers of payment of remuneration) to healthcare professionals to encourage prescribing Zofran for pregnancy-related nausea;

(j) Failing to correct the misrepresentation that Zofran is safe and effective for treating pregnancy-related nausea and vomiting; and

(k) Failing to correct the misrepresentation that Zofran is a safe and effective prophylactic measure for preventing morning sickness.

67. Because of the devastating impact that a birth defect has on the child and the child's family, Defendants should have promptly disclosed any increase in birth defect risk arising from prenatal exposure to Zofran. Defendants knew or should have known that consumers, such as Plaintiffs and their minor children, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable care.

68. Defendants' negligence was the proximate cause of Plaintiffs' injuries, harm, and economic loss, which Plaintiffs and their minor children suffered and/or will continue to suffer.

69. Had Plaintiffs not taken Zofran, Plaintiffs' minor children would not have suffered those injuries and damages as described with particularity in the Short Form Complaint. Had GSK marketed Zofran in a truthful and non-misleading manner and/or had Defendants corrected the misrepresentations and adequately warned, Plaintiffs would never have taken Zofran.

70. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs' minor children suffered birth defects, physical pain, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

SECOND CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

71. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs

plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

72. Defendants falsely and negligently misrepresented material facts on which Plaintiffs and their healthcare providers acted.

73. Defendants also failed to disclose material facts regarding the safety and efficacy of Zofran use to treat morning sickness.

74. Defendants 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 Plaintiffs and their healthcare providers.

75. Defendants 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 Plaintiffs and their healthcare providers.

76. In violation of existing standards and duties of care, Defendants made misrepresentations through their advertisements, labeling, marketing, marketing persons, notices, product information, and written and oral information provided to patients and medical providers.

77. Defendants negligently represented to the expectant mothers and the medical and healthcare community, including Plaintiffs and their healthcare providers, that:

(a) Animal studies of ondansetron showed no harm to fetuses;

(b) Zofran should be used during pregnancy if it is clearly needed, without limiting that representation to situations where it is clearly needed for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting, or post-operative nausea and/or vomiting;

(c) As to GSK, Zofran was safe and effective for treating pregnancy-related nausea and vomiting;

(d) As to GSK, Zofran was a safe and effective prophylactic treatment for preventing pregnancy-related nausea and vomiting;

(e) As to GSK, Zofran had been adequately tested and studied in pregnant women; and

(f) As to GSK, Zofran use during pregnancy did not increase the risk of birth defects.

78. The representations were material, false, misleading, and made with actual or constructive knowledge that they were false. Defendants have failed to correct each of these misrepresentations.

79. When Plaintiffs used Zofran, they were unaware of the falsity of said representations and reasonably believed them to be true.

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

81. Defendants' labeling of Zofran was also rendered misleading by the omission of the material risk information listed in the preceding count.

82. Plaintiffs and their healthcare providers justifiably relied on Defendants' representations and non-disclosures when ingesting Zofran.

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

84. Defendants knew or should have known that use of Zofran by expectant mothers' increases the risk of developing birth defects.

85. Defendants knew or should have known that consumers, such as Plaintiffs, would foreseeably use Zofran and that they and their prescribing healthcare provider would rely upon the representations and omissions.

86. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs' minor children suffered birth defects, physical pain, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

THIRD CAUSE OF ACTION
NEGLIGENT UNDERTAKING

87. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

88. Beginning as early as 1997, GSK promoted Zofran as a safe and effective treatment for pregnancy-related nausea and vomiting. In view of this promotion and Defendants' knowledge of same, they undertook a duty to:

(a) Adequately monitor and respond to the post-market pregnancy risks arising from use of Zofran to treat morning sickness;

(b) Perform adequate testing to assess the safety and efficacy of the drug for treating pregnancy-related nausea;

(c) Disclose their knowledge that Zofran ingested during pregnancy readily crosses a pregnant mother's placental barrier and exposes fetuses to substantial concentrations of Zofran for longer durations than the mother's exposure;

(d) Disclose their knowledge that Zofran has been shown to inhibit the human embryo's serotonin activity, and that such serotonin activity regulates developmental processes that are essential to normal embryonic development;

(e) Disclose their knowledge that Zofran's established side effects in adults can also occur in embryos and fetuses, leading to birth defects;

(f) Disclose their knowledge that Zofran's established side effects in adults can also occur in embryos and fetuses in combination with other drugs that have the same side effects, leading to birth defects;

(g) Disclose reports of birth defects associated with Zofran to providers and consumers;

(h) Correct the misrepresentation that Zofran is safe and effective for treating pregnancy-related nausea and vomiting; and

(i) Correct the misrepresentation that Zofran is a safe and effective prophylactic measure for preventing morning sickness.

89. Upon acquiring the Zofran product portfolio, Novartis assumed the same duties.

90. Defendants should have recognized and reasonably foreseen that the accuracy and sufficiency of Zofran warnings—and other written and verbal information regarding the use of Zofran for pregnancy-related nausea and vomiting conveyed to healthcare professionals—was necessary for the protection of pregnant patients and their unborn children, like Plaintiffs here, and for the proper performance of Defendants' undertaken duties to them.

91. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs' minor children suffered birth defects, physical pain, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

FOURTH CAUSE OF ACTION
NEGLIGENCE PER SE

92. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing

paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

93. Defendants had a duty to exercise reasonable care and comply with existing standards in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of Zofran, and post-market vigilance regarding same.

94. Defendants failed to exercise reasonable care and failed to comply with existing laws in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of Zofran, and post-market vigilance regarding same.

95. Under federal law governing labeling for Zofran, Defendants were 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) (amended and re-codified on June 30, 2006 at 21 C.F.R. § 201.80(e)), for drugs approved before June 30, 2001, including Zofran). Defendants also were required to list adverse reactions that occurred with other drugs in the same class as Zofran. *Id.* § 201.57(g) (re-codified on June 30, 2006 at 21 C.F.R. § 201.80(g), for drugs approved before June 30, 2001). Breaches of these duties constitute independent acts of negligence under state law.

96. Federal law also required Defendants 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) (re-codified on June 30, 2006 at 21 C.F.R. § 201.80(e), for drugs approved before June 30, 2001). Under 21 C.F.R. § 314.70(c)(6)(iii), pharmaceutical companies were (and are) free to add or strengthen – without

prior approval from the FDA – a contraindication, warning, precaution, or adverse reaction, as soon as there was reasonable evidence of an association of a serious hazard with the drug, *id.* § 201.57(e)), and to delete false, misleading, or unsupported indications for use or claims for effectiveness. Breach of this duty is an independent breach of state law.

97. Defendants failed to exercise reasonable care and violated 21 U.S.C. §§ 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.80, and 201.128, in particular. The violations constitute independent violations of state negligence law.

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

99. Despite the fact that Defendants knew or should have known that Zofran significantly increased the risk of birth defects, Defendants continued and continue to negligently market and label Zofran.

100. Defendants knew or should have known that consumers, such as Plaintiffs and their minor children, would foreseeably suffer injury as a result of Defendants' failures to exercise reasonable care, as set forth above.

101. Defendants' negligence was the proximate cause of Plaintiffs' and their minor children's injuries, harm, and economic loss, which Plaintiffs and their minor children suffered and/or will continue to suffer.

102. Had Plaintiffs not taken Zofran, their children would not have suffered injuries and damages.

103. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs' minor children suffered birth defects, physical pain, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

FIFTH CAUSE OF ACTION
FAILURE TO WARN - STRICT LIABILITY

104. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

105. Zofran was manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants and was defective at the time it left Defendants' 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.

106. Defendants failed to provide adequate warnings to healthcare providers and users, including Plaintiffs and their healthcare providers, of the increased risk of birth defects associated with Zofran.

107. Prescribing physicians, healthcare providers and mothers-to-be, including Plaintiffs and their healthcare providers, neither knew, nor had reason to know at the time of their use of Zofran, of the existence of the aforementioned defects. Ordinary consumers would not have recognized the potential risks or side effects for which Defendants failed to include appropriate warnings, and which Defendants concealed.

108. The Zofran ingested by Plaintiffs was neither misused nor materially altered.

109. Defendants are strictly liable for failure to warn by virtue of its conduct of selling a product that is unreasonably dangerous and for failing to provide an adequate warning about Zofran.

110. Defendants are therefore strictly liable by virtue of the following acts and/or omissions:

(a) Failing to adequately and correctly warn the Plaintiffs, the public, and the medical and healthcare communities of the dangers of Zofran for pregnant women and their children;

(b) Failing to disclose their knowledge that Zofran ingested during pregnancy readily crosses a pregnant mother's placental barrier and exposes fetuses to substantial concentrations of Zofran for longer durations than the mother's exposure;

(c) Failing to disclose their knowledge that Zofran has been shown to inhibit the human embryo's serotonin activity, and that such serotonin activity regulates developmental processes that are essential to normal embryonic development;

(d) Failing to disclose their knowledge that Zofran's established side effects in adults can also occur in embryos and fetuses, leading to birth defects;

(e) Failing to disclose their knowledge that Zofran's established side effects in adults can also occur in embryos and fetuses in combination with other drugs that have the same side effects, leading to birth defects;

(f) Failing to disclose reports of birth defects associated with Zofran to providers and consumers;

(g) Failing to correct the misrepresentation that Zofran is safe and effective for treating pregnancy-related nausea and vomiting; and

(h) Failing to correct the misrepresentation that Zofran is a safe and effective prophylactic measure for preventing morning sickness.

111. Had Plaintiffs and their providers been adequately warned of the increased risk of birth defects associated with Zofran, Plaintiffs would not have taken Zofran.

112. Had Plaintiffs not taken Zofran, their children would not have suffered those injuries and damages as described with particularity in the Short Form Complaint.

113. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs' minor children suffered birth defects, physical pain, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

114. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

115. GSK expressly warranted through its marketing to healthcare providers and consumers that Zofran was safe and effective for treating pregnancy-related nausea and vomiting and had been adequately tested.

116. Zofran did not conform to GSK'S express warranties because it has serious side effects and has not been adequately tested.

117. At the time of the making of the express warranties, GSK knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its warranted use.

118. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs, relied upon the representations and warranties of GSK for use of Zofran in recommending, prescribing, and/or dispensing Zofran.

119. As a direct and proximate result of the foregoing breaches, Plaintiffs' minor children were caused to suffer dangerous birth defects, as well as other permanent personal injuries, physical pain, mental anguish, and diminished enjoyment of life, and the need for lifelong medical treatment, monitoring and/or medications.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

120. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

121. Defendants impliedly warranted to the users of Zofran and their healthcare providers that Zofran was safe and fit for use for the treatment of pregnancy-related nausea and vomiting.

122. Defendants breached the implied warranties, as Zofran was not fit for the treatment of pregnancy-related nausea or vomiting.

123. Defendants were aware that consumers, including Plaintiffs, would use Zofran for the purpose intended and warranted by Defendants.

124. Zofran reached consumers, including Plaintiffs, without substantial change in the condition in which it was manufactured and sold by Defendants, and the Zofran was neither misused nor materially altered.

125. Plaintiffs and their physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Zofran was of merchantable quality and safe and fit for its intended use.

126. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs' minor children suffered birth defects, physical pain, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

EIGHTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION AND CONCEALMENT

127. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

128. Defendants fraudulently represented to expectant mothers and the medical and healthcare community, including Plaintiffs and their providers, that:

(a) Animal studies of ondansetron showed no harm to fetuses;

(b) Zofran should be used during pregnancy if it is clearly needed, without limiting that representation to situations where it is clearly needed for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting, or post-operative nausea and/or vomiting;

(c) As to GSK, Zofran was safe and effective for treating pregnancy-related nausea and vomiting;

(d) As to GSK, Zofran was a safe and effective prophylactic treatment for preventing pregnancy-related nausea and vomiting;

(e) As to GSK, Zofran had been adequately tested and studied in pregnant women; and

(f) As to GSK, Zofran use during pregnancy did not increase the risk of birth defects.

129. The representations were material, false, misleading and made with actual or constructive knowledge that they were false.

130. When these representations were made, Defendants knew the representations were false and misleading.

131. Defendants made these representations with the intent of defrauding and deceiving healthcare providers and Plaintiffs to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy-related nausea and vomiting.

132. When Plaintiffs ingested Zofran, they and their healthcare providers were unaware of the falsity of said representations and reasonably believed them to be true.

133. In reasonable reliance upon said representations, Plaintiffs' providers were induced to prescribe Zofran to Plaintiffs and recommend the drug as safe for treating pregnancy-related nausea, and Plaintiffs were induced to and did ingest Zofran to treat pregnancy-related nausea. Had Defendants not made the false statements about the drug, Plaintiffs would not have used the product and their medical providers would not have administered it and recommended it as safe.

134. Defendants are and were under a continuing duty to monitor and disclose the risks of Zofran use during pregnancy. They have fraudulently concealed the risks and their knowledge of them. Defendants' fraudulent concealment was designed to prevent, and did prevent, the public and the medical community at large from discovering the risks and dangers associated with Zofran use for treating morning sickness. Their fraudulent concealment also prevented Plaintiffs from discovering, and/or with reasonable diligence being able to discover, their causes of action.

135. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs' minor children suffered birth defects, physical pain, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

NINTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS

136. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

137. GSK, through the use of false and/or misleading advertising, representations and statements, and Defendants, through their failures to correct the same, induced Plaintiffs, individually or through their healthcare providers, to use and consume Zofran. Defendants have violated state consumer protection laws, which prohibit, among other things:

(a) Engaging in unfair trade practices as defined in these statutes by making false and misleading written statements that have the capacity, tendency or effect of deceiving or misleading consumers;

(b) Engaging in unfair trade practices as defined in these statutes by making representations that their products had a use or benefit which they did not have, including, but not limited to, statements concerning the health consequences of Zofran use;

(c) Engaging in unfair trade practices as defined in these statutes by failing to state material facts, the omission of which deceive or tend to deceive, including but not limited to, facts relating to the health consequences of Zofran use; and

(d) Engaging in unfair trade practices as defined in these statutes through deception, fraud, misrepresentation, and knowing concealment, suppression, and omission of material facts with the intent that consumers rely upon the same in connection with Zofran use.

138. Plaintiffs specifically incorporate the foregoing misrepresentations and omissions listed in preceding counts as unfair and deceptive practices in violation of state consumer protection laws.

139. As a direct and proximate result of the aforesaid statutory violations, Plaintiffs were injured and damaged as described in the Short Form Complaint.

140. Defendants' conduct was willful and knowing, and accordingly, they are liable for multiple damages and/or penalties pursuant to applicable state consumer protection laws.

TENTH CAUSE OF ACTION
WRONGFUL DEATH

141. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

142. Plaintiffs bring this claim on behalf of the Estate of their minor children and seek damages for Decedent's lawful beneficiaries.

143. As a direct and proximate result of Defendants' conduct as discussed in detail in this Brand Master Complaint, Decedent suffered bodily injury resulting in death.

144. Plaintiffs have standing to bring this wrongful death action pursuant to applicable state law.

145. As a direct and proximate result of Defendants' conduct, Decedent's beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a

result of Decedent's death. Plaintiffs bring this claim for these damages and for all pecuniary losses sustained by said beneficiaries pursuant to the applicable state law pursuant to choice of law principles, pleaded in the broadest sense.

ELEVENTH CAUSE OF ACTION
SURVIVAL ACTION

146. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

147. As a direct and proximate result of Defendants' conduct, Decedents were caused pain and suffering, mental anguish, and impairment of the enjoyment of life, until the date of death; and, as a direct and proximate result of the aforesaid, Decedents suffered a loss of earning capacity.

148. This claim is brought on behalf of the Decedents pursuant to all applicable state law pursuant to choice of law principles, pleaded in the broadest sense.

149. Plaintiffs have standing to bring this survival action under applicable state law.

TWELFTH CAUSE OF ACTION
LOSS OF CONSORTIUM

150. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense,

pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

151. As a direct and proximate result of Defendants' negligence and wrongful conduct, Plaintiffs have been deprived of the society, love, affection, companionship, care and services, of their children and are entitled to recovery for said loss pursuant to all applicable laws pursuant to choice of law principles, pleaded in the broadest sense.

152. Plaintiffs seek all damages available against Defendants on account of their loss of their minor children's consortium.

THIRTEENTH CAUSE OF ACTION
PUNITIVE DAMAGES

153. Plaintiffs, individually and on behalf of their minor children, repeat each allegation of this Brand Master Complaint and Jury Demand contained in the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. Plaintiffs plead all Counts of this Brand Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws pursuant to choice of law principles, including the law of the each Plaintiff's home state.

154. Plaintiffs are entitled to punitive damages because Defendants' actions were reckless and showed a conscious regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiffs, by making false representations and by concealing pertinent information regarding Zofran. Defendants downplayed, understated, and disregarded their knowledge of the serious and permanent risks associated with the use of Zofran, despite being on notice of information demonstrating that the product was unreasonably dangerous.

155. Defendants have risked the lives, health and well-being of patients by suppressing knowledge of the risks of Zofran from the general public. Defendants made a conscious decision not to warn or correct the misrepresentations and omissions alleged herein to unsuspecting mothers-to-be and healthcare providers.

156. The conduct of Defendants in researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of Zofran, and post-market vigilance regarding same, and in failing to warn Plaintiffs and other members of the public of the dangers inherent in the use of Zofran, which were known to Defendants, was attended by circumstances of malice, avarice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences or to the rights and safety of others, including Plaintiffs.

157. Defendants breached their duties and were wanton and reckless in their actions and omissions toward the public generally, and Plaintiffs specifically.

158. Defendants' conduct was committed with gross negligence and conscious and deliberate disregard for the rights and safety of consumers, including Plaintiffs, or with such wanton and/or reckless disregard, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

DEMAND FOR JURY TRIAL

Each 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, each Plaintiff demands judgment against Defendants 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 consequential damages in excess of the jurisdictional minimum of this Court;

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

(f) For statutory damages as allowed under state law, including state consumer protection laws;

(g) For punitive damages in an amount sufficient to deter similar conduct in the future and punish Defendants for the conduct described herein;

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

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

Dated: May 31, 2016

Respectfully submitted,

/s/ Robert K. Jenner

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Brand Master Long Form Complaint and Jury Demand, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF"), and paper copies will be sent via first class mail to those identified as non-registered participants.

/s/ **Robert K. Jenner**
Robert K. Jenner