EXHIBIT C

Denver District Court Denver County, Colorado 1437 Bannock Street Denver, CO 80202 Plaintiff(s): STEPHANIE MARTINEZ v. Defendant(s): MICHAEL DIMARIA, M.D. AND GLAXOSMITHKLINE, LLC	DATE FILED: August 14, 2015 4:57 PM FILING ID: 4541AEE52B45F CASE NUMBER: 2015CV32911 COURT USE ONLY
Attorney: Julia Thompson Schoenwald & Thompson LLC Address: 1890 Gaylord Street Denver, CO 80206 Phone Number: (303) 837-9000 Fax Number: (303) 322-3423 E-mail: juliat@milehighlaw.com Atty. Reg. Nos: 25897	Case Number: Division Courtroom
COMPLAINT	

Plaintiff Stephanie Martinez by and through the undersigned counsel hereby submits this Complaint against Michael DiMaria, M.D. and GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "Defendant"). The Plaintiff alleges and avers the following:

I. PARTIES

1. Plaintiff Stephanie Martinez is a resident and citizen of the State of Colorado.

2. Plaintiff Stephanie Martinez is the mother of Sophia Martinez ("S.M."), who was born on July 20, 2013 and died on August 15, 2013.

3. At all relevant times, Michael DiMaria, M.D. was a physician licensed to practice in the State of Colorado.

4. GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("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.[1] GSK is registered to conduct business in Colorado, with a Resident Agent located in Denver, Colorado.

5. On November 19, 2012, Plaintiff had a positive pregnancy test.

6. Plaintiff began to experience morning sickness during her pregnancy and was prescribed Zofran which she took from approximately December 2012 thru July 2013.

7. On July 20, 2013, Sophia Martinez was born at Lutheran Medical Center with apgars of 8 and 9.

8. At or around the time of her birth, Sophia Martinez was diagnosed with a heart murmur.

9. On August 6, 2013, S.M. was diagnosed with a heart murmur by her pediatrician and a referral was made to Defendant DiMaria.

10. On August 8, 2013, S.M. was evaluated by Defendant DiMaria and he performed an echocardiogram and diagnosed her with diagnosed Sophia with peripheral pulmonary arteriosis and a heart murmur.

11. On August 8, 2013, Defendant DiMaria knew or should have known that Plaintiff had taken Zofran during her pregnancy with S.M.

12. On August 8, 2013, Defendant DiMaria recommended no further care for S.M. except to follow-up in one month.

13. On August 15, 2013, S.M. died as a result of untreated patent foramen ovale and patent ductus arteriosis in Jefferson County, Colorado.

14. As a result of the negligence of Defendant DiMaria in his care and treatment of S.M. she died and Plaintiff suffered injuries, damages and losses.

15. Zofran is a powerful drug developed by GSK to treat only those patients who were afflicted with the most severe nausea. This includes, for example, nausea associated with cancer treatment such as radiation or chemotherapy.

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

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[1] The term GSK is intended to collectively refer to GSK, its predecessors Glaxo, Inc. and Glaxo Wellcome Inc., and all other predecessors and/or affiliates that discovery will reveal were involved in either the development, testing, manufacture, distribution, marketing or sale of Zofran at any time relevant to the actions or inactions referenced in this complaint. Plaintiff reserves the right to amend to add additional parties as they are discovered.

17. The use of Zofran by women who are pregnant increases the risk of birth defects.

18. Although the only FDA approval for this drug was for seriously ill, badly suffering cancer patients, GSK marketed Zofran "off label" as a safe and effective treatment for the very common side effect of a normal pregnancy - pregnancy-related nausea and vomiting ("Morning Sickness").

19. Prior to marketing Zofran as an off label treatment for Morning Sickness, GSK had the duty at all times to eliminate, minimize or warn of the risk of birth defects.

20. At all the times it marketed Zofran as an off label treatment for Morning Sickness, GSK had the duty to warn eliminate, minimize or warn of the risk of the birth defects.

21. Between 1991 and 2011, GSK had the duty at all times to eliminate, minimize or warn of the risk of birth defects.

22. Between 1991 and 2011, GSK did not warn the consuming public that taking Zofran during pregnancy created a risk of birth defects.

23. Between 1991 and 2011, GSK did not act to minimize the risk of birth defects caused by taking Zofran during pregnancy.

24. Between 1991 and 2011, GSK did not act to eliminate the risk of birth defects caused by taking Zofran during pregnancy.

25. GSK marketed Zofran "off label" as a safe and effective Morning Sickness treatment despite having knowledge that such a representation was utterly false.

26. Expecting mothers have many concerns to consider that relate to the health of their developing babies. Diet, stress level and general health all affect an unborn baby in its mother's womb, but which drugs a mother chooses to put into her body, if any, can potentially have an enormous impact on the long term health of the child.

27. While in the womb, a fetus grows and develops in reliance upon the nourishment received from the mother via the placenta. However, along with nutrients, any toxins in the mother's system may be delivered to the fetus. These toxins may cause damage to the developing fetal organs.

28. Ever since the 1960s when thalidomide, a sleep aid and morning-sickness drug, was linked to more than 10,000 babies born with missing or shrunken limbs, it has been known that the medications a pregnant woman takes can cross the placenta and affect her unborn child.

29. GSK marketed Zofran "off label" as a safe and effective Morning Sickness treatment despite having knowledge that such representations were utterly unsupported and unproven and despite actual knowledge of the increased risk that medication a pregnant woman takes can cross the placenta and affect her unborn child.

30. During the years 1991 through 2011, all other FDA-approved Morning Sickness prescription drugs in the United States went through the clinical trial process before being marketed to pregnant women.

31. GSK never carried out a single study on the effects of this powerful drug on a pregnant mother or her growing fetus prior to marketing Zofran as a safe and effective “off label” Morning Sickness treatment.

32. GSK knew as early as 1992 that Zofran passed through the placenta and into a developing fetus.

33. GSK knew as early as 1992 that Zofran presented "unreasonable risk of harm" to developing babies because the drug passes through the human placenta.

34. Between 1992 and 2011, GSK gained additional knowledge that Zofran presented an "unreasonable risk of harm" to developing babies.

35. Notwithstanding this actual knowledge, GSK continually marketed the drug to pregnant woman from 1992 through 2011.

36. In 1992, GSK had no scientifically conclusive data that established that Zofran did not present an "unreasonable risk of harm" to developing babies because the drug passes through the human placenta.

37. At no time between 1992 and 2011 did GSK possess scientifically conclusive data establishing that Zofran did not present an "unreasonable risk of harm" to developing fetuses.

38. Notwithstanding its actual knowledge, GSK continually marketed the drug to pregnant woman from 1992 through 2011.

39. At times between 1992 and 2011, GSK avoided conducting studies or trials because they would have hampered its marketing of Zofran and decreased profits.

40. At times between 1992 and 2011, linking Zofran to serious birth defects would have hampered its marketing of Zofran and decreased profits.

41. Plaintiff was harmed by the actions of Defendant GSK prior to the birth of S.M. in 2013.

42. In 2012, GSK pled guilty to charges of fraud and illegal promotion of several drugs, including Zofran, that were prosecuted by federal authorities.

43. GSK agreed to pay a $3 billion fine as part of the legal settlement. This fine was among the largest fines in United States’ history.

44. Plaintiff's minor child, S.M., was born in 2013 with numerous congenital defects after her mother had been prescribed and took Zofran to alleviate the symptoms of Morning Sickness while pregnant.

45. Immediately after birth, S.M. was diagnosed with a heart murmur.

46. On August 15, 2013, S.M. died from complications of patent foramen ovale and patent ductus arteriosus.

47. Had Plaintiff known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, she would never have taken Zofran, and her child would not have been caused to directly and proximately suffer related injury resulting in death.

48. In the United States, payments to doctors, other medical providers and health care institutions by major pharmaceutical companies such as GSK for the purposes of promotion and marketing is a multi-billion dollar industry.

49. In 2013, GSK made $12.8 billion in sales in the United States, making it the fifth most lucrative pharmaceutical company doing business in the United States according to IMS Health. *See* http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/Press%20Room/Global_2013/Top_20_Global_Corporations_2013.pdf.

50. In 2015, GSK was ranked #265 by revenue of the Fortune 500 list of top U.S. companies. Its stock trades on the New York Stock Exchange under the symbol GSK. *See* http://fortune.com/global500/glaxosmithkline-265/.

51. Between April 2009 and December 2013, GSK voluntarily self-reported that it made payments totaling over $437.9 million dollars in the United States for speaking fees, consulting fees, research, travel fees and meals.

52. GSK did not disclose the amount it paid for educational items, gifts, or royalty or licensing fees. *See* ProPublica, at http://projects.propublica.org/docdollars/.

53. GSK did not disclose the amount it paid in Colorado for educational items, gifts, or royalty or licensing fees. During this period, GSK spent $7,101.672 in Colorado in promotional and marketing activities. *See* ProPublica, at http://projects.propublica.org/docdollars/companies/glaxosmithkline.

54. GSK is the successor in interest to Glaxo, Inc. and Glaxo Wellcome Inc.

55. Glaxo, Inc. sponsored the original New Drug Application ("NDA") for Zofran.

56. Cerenex Pharmaceuticals, a division of Glaxo, Inc., authored the original package insert and labeling for Zofran, including its warnings and precautions.

57. Glaxo Wellcome Inc. sponsored additional NDAs for Zofran.

58. Glaxo Wellcome Inc. monitored and evaluated post-market adverse event reports arising from Zofran, and authored product labeling for Zofran.

59. Zofran is an effective drug to treat patients afflicted with severe nausea and vomiting resulting from the effects of radiation or chemotherapy in cancer treatment.

60. The U.S. FDA approved Zofran in 1991 for the treatment of such seriously ill patients.

61. GSK marketed Zofran "off-label."

62. GSK represented that Zofran was a safe and effective treatment for the nausea and vomiting associated with pregnancy.

63. Zofran had not been studied for its adverse affects upon a pregnant mother, or the possible teratogenic effects upon a fetus at any time between 1991 and 2011.

64. According to the Merck Manual, more than 50% of pregnant women take prescription or nonprescription (over-the-counter) drugs or use social drugs (such as tobacco and alcohol) or illicit drugs at some time during pregnancy, and use of drugs during pregnancy is increasing. In general, drugs should not be used during pregnancy unless absolutely necessary because many can harm the fetus. About 2 to 3% of all birth defects result from drugs that are taken to treat a disorder or symptom.

65. The medical and pharmacological communities accept as fact that drugs taken by a pregnant woman reach the fetus primarily by crossing the placenta, the same route taken by oxygen and nutrients, which are needed for the fetus's growth and development.

66. The medical and pharmacological communities accept as fact that drugs that a pregnant woman takes during pregnancy can affect the fetus in several ways including:

a. They can act directly on the fetus, causing damage, abnormal development (leading to birth defects), or death;

b. They can alter the function of the placenta, usually by causing blood vessels to narrow (constrict) and thus reducing the supply of oxygen and nutrients to the fetus from the mother. Sometimes the result is a baby that is underweight and underdeveloped;

c. They can cause the muscles of the uterus to contract forcefully, indirectly injuring the fetus by reducing its blood supply or triggering preterm labor and delivery;

d. They can also affect the fetus indirectly. For example, drugs that lower the mother's blood pressure may reduce blood flow to the placenta and thus reduce the supply of oxygen and nutrients to the fetus; and

e. Some of the fetus's blood vessels are contained in tiny hairlike projections (villi) of the placenta that extend into the wall of the uterus. The mother's blood passes through the space surrounding the villi (intervillous space). Only a thin membrane

(placental membrane) separates the mother's blood in the intervillous space from the fetus's blood in the villi. Drugs in the mother's blood can cross this membrane into blood vessels in the villi and pass through the umbilical cord to the fetus.

67. Often, a safer drug can be substituted for one that is likely to cause harm during pregnancy. If not, the safest alternative is not to take any drug.

68. GSK simply chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment of pregnant women.

69. Prior to 2012, GSK did not carry out the study of the risks presented by the use of Zofran's effects during pregnancy because it had knowledge of the drug's toxicity and the studies would have impeded the drug's marketability and profits.

70. The birth defects caused by the use of Zofran by pregnant women, including Plaintiff, will have devastating effects upon their affected children, including serious and disabling permanent injury.

71. Studies have identified the following potential dangers when Zofran is taken in the first trimester of pregnancy:

a 2.37 times increased risk of cleft palate;
b. 2 times increased risk of heart defect; and
c. 20% increased risk of any birth defect.

72. Plaintiff ingested Zofran because she was deceptively led to believe that Zofran was an appropriate drug for her use while she was pregnant.

73. Plaintiff relied upon the statements of GSK and was not in position to independently verify the safety or effectiveness of Zofran as it related to herself or her unborn child S.M.

74. Plaintiff relied upon the statements of GSK and was not in position to independently verify whether it was a safe and effective treatment for pregnancy-related nausea.

75. GSK knew that Zofran was unsafe for ingestion by expectant mothers.

76. For example, in the 1980s, GSK conducted animal studies that revealed evidence of toxicity, intrauterine deaths and malformations in offspring.

77. The 1980's studies further showed that Zofran's active ingredient transferred through the placental barrier of pregnant mammals to fetuses.

78. A later study conducted in humans confirmed that ingested Zofran readily crossed the human placenta barrier and exposed fetuses to substantial concentrations.

79. GSK did not disclose this information to the public, Plaintiff, or her physicians.

80. By 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran.

81. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date.

82. GSK never disclosed these reports to pregnant women or their physicians.

83. In addition, scientists have conducted large-scale epidemiological studies on Zofran that have demonstrated an elevated risk of developing birth defects such as those suffered in this case.

84. GSK has not disclosed this to pregnant women, their physicians or the public. Instead, GSK sales representatives specifically marketed and promoted Zofran as a Morning Sickness drug throughout all relevant time periods discussed herein.

85. This was not all however. GSK also knowingly and willfully acted unfairly, deceptively or in bad faith by underreporting related injuries it received notice of.

86. 42 U.S.C. § 1320a-7b, the Federal Anti-Kickback Statute, makes it illegal to promote certain drugs with various forms of remuneration, including cash payments disguised as consulting fees, expensive meals, weekend boondoggles and lavish entertainment to prescribers and other health care professionals to induce them to prescribe and recommend drugs, including those paid for by federal health care programs.

87. Pharmaceutical companies such as GSK are required to follow a multitude of stringent industry standards and rules established by and according to the FDA.

88. The Physician Payments Sunshine Act (the "PPSA"), section 6002 of the Affordable Care Act of 2010, requires medical product manufacturers to disclose to the Centers for Medicare and Medicaid Services ("CMS") any payments or other transfers of value made to physicians or teaching hospitals.

89. The PPSA, section 6002 of the Affordable Care Act of 2010, also requires certain manufacturers and group purchasing organizations ("GPOs") to disclose any physician ownership or investment interests held in those companies.

90. The PPSA, section 6002 of the Affordable Care Act of 2010, was intended to make the financial relationships between doctors, hospitals, and health care manufacturing companies more transparent.

91. These requirements include any payment to doctors over $10, beginning on September 30, 2014. That information is posted on a website hosted by the CMS. *See* http://www.cms.gov/openpayments/index.html.

92. In recent years, the United States' government has made major alterations to its prosecution through the Department of Justice (the "DOJ") of pharmaceutical corporations to change those companies' practice of promotion and marketing.

93. Major pharmaceutical companies have agreed to pay over $13 billion to resolve U.S. DOJ allegations of fraudulent marketing practices, including the promotion of medicines for uses that were not approved by the FDA. *See* http://projects.propublica.org/graphics/bigpharma.

94. The DOJ filed a Complaint against GSK on October 26, 2011 in the United States District Court for the District of Massachusetts, C.A. No. 11-10398-RWZ.

95. In its Complaint, the DOJ stated the following: From 1999 through 2010 in some instances, GSK engaged in a fraudulent scheme to deceive and defraud physicians, patients, regulators, and federal health care programs to cause prescribing and payment for certain of GSK's drugs. This conduct includes repeatedly publishing and promoting false and misleading accounts of studies and treatment guidelines to convince physicians to use GSK drugs.

96. GSK misrepresented clinical evidence, downplayed or ignored safety risks, and failed to disclose the rejection by the United States FDA of some of the exact claims GSK was making to physicians. GSK promoted these products for uses that the FDA had not approved as safe and effective ("off-label" or "unapproved" uses), and for uses that were not medically accepted indications covered by federal health care programs.

97. GSK also used a wide variety of gifts, payments and other remuneration to induce physicians to prescribe GSK's drugs, including trips to Bermuda and Jamaica, spa treatments and hunting trips, and sham consulting fees. The Complaint filed by the DOJ further alleged that GSK promoted certain GSK drugs with various forms of "illegal remuneration, including cash payments disguised as consulting fees, expensive meals, weekend boondoggles, and lavish entertainment to prescribers and other health care professionals to induce them to prescribe and recommend GSK's drugs, including those paid for by federal health care programs, all in violation of the federal anti-kickback statute 42 U.S.C. § 1320a-7b." (Complaint, p. 2, October 26, 2011)

98. GSK's subsequent settlement agreement with the DOJ binds GSK's to the many admissions against interest. The settlement agreement stated:

> [t]he United States contends that it and the Medicaid Participating States have certain civil claims, as specified in Paragraph 2, below, against GSK for engaging in the conduct set forth in the Complaint-in-Intervention and as described as follows (hereinafter referred to as the "Covered Conduct"): ...**Zofran**: During the period of January 1, 2002 through December 31, 2004, GSK knowingly: (a) promoted the sale and use of Zofran for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including hyperemesis or

> pregnancy-related nausea), and some of which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Zofran;(b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Zofran concerning the uses described in section (a) of this sub-paragraph; and (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, GSK knowingly caused false or fraudulent claims for Zofran to be submitted to, or cause purchases by Medicaid and the other Federal Health Care Programs. (Settlement Agreement, p. 5, July 2, 2012.)

99. As part of its arrangement with the DOJ, GSK agreed to plead guilty to two counts of introducing misbranded drugs and one count of failing to report safety data to the FDA.

100. GSK was also under investigation for bribing doctors in China to prescribe its products and using travel agencies to cover up the practice.

101. GSK has admitted to some instances, saying that it appears that some senior executives in China appeared to have violated Chinese law. *See* http://www.gsk.com/media/press-releases/2013/gsk-statement-regarding-recent-meeting-with-chinese-authorities.

102. In a press release dated July 2, 2012, the DOJ explained its global resolution with GSK for an amount of $3 billion dollars, which the DOJ explained as "the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company."

103. The DOJ explained: "As part of this global resolution, GSK has agreed to resolve its civil liability for the following alleged conduct: (1) promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex.

104. The settlement further explained that "[it] further resolves allegations that GSK promoted certain forms of Zofran, approved only for post-operative nausea, for the treatment of morning sickness in pregnant women."

105. The settlement also resolved allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe Paxil, Wellbutrin, Advair, Lamictal and Zofran as well as the drugs Imitrex, Lotronex, Flovent and Valtrex.

106. The United States alleged that GSK's conduct caused false claims to be submitted to federal health care programs." *See* http://www.justice.gov/opa/pr/glaxosmithkline- plead-guilty-and-pay-3-billion-resolve-

fraud-allegations-and-failure-report (emphasis added).

107. After the plea arrangement made with the DOJ and the passage of the PPSA, GSK claimed it made major alterations to its business model. The fact that it admitted to the necessity of making major alterations establishes that its prior system was deficient.

108. GSK also indicated that it would no longer hire doctors to promote its products and that it would disclose its clinical trial data to researchers.

109. GSK also stated that it would end its practice of tying compensation for sales representatives to the number of prescriptions written for the drugs they market or sell.

110. The company had self-reported that its budget for speaking engagements went from $24 million in 2011 to $9.3 million in 2012.

111. GSK admitted that these and other comprehensive changes would be instituted worldwide over the next several years. *See* ProPublica, http://www.propublica.org/article/glaxosmithkline-to-quit-paying-doctors-for-promotional-talks

112. Between 1991 and 2012, GSK offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran.

113. In 2012, GSK pled guilty to criminal charges lodged by the United States of America, through the DOJ, for its "off-label" promotion of its drugs, including Zofran, for uses never approved by the FDA.

114. As referenced above, at or around the same time, GSK also entered civil settlements with the Department of Justice that included more than $1 billion in payments to the federal government for its illegal marketing of various drugs, including Zofran specifically.

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

116. As referenced above, between 2002 and 2012, GSK offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran.

117. GSK's conduct has caused devastating, irreversible, and life-long consequences for and suffering to innocent newborns and their families, as exemplified by Plaintiff herein. Plaintiff brings claims for compensatory and punitive damages, as well as equitable relief in an effort to ensure that similarly situated mothers-to-be are fully informed about the risks, benefits and alternatives attending drugs marketed for use in pregnant women, and such other relief deemed just and proper arising from injuries and birth defects as a result of exposure to Zofran.

118. 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, the company 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.

119. In a published study involving forty-one pregnant patients, 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 fact, the study reported that the average fetal tissue concentration of Zofran's active ingredient was 41% of the corresponding concentration in the mother's plasma.

120. 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.

121. GSK stated that the preclinical teratogenicity studies in rats and rabbits showed no harm to the fetus.

122. Contrary to GSK's statements, the data revealed clinical signs of toxicity, premature births, intrauterine fetal deaths and impairment of ossification (incomplete bone growth).

123. 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 were observed in the pregnant rats included "low posture, ataxia, subdued behavior and rearing, as well as nodding and bulging eyes." No observations were reported as teratogenic effects.

124. Study No. R10873 was a Segment II teratological study of pregnant rabbits exposed to Zofran injection solution. Four groups of 15 pregnant rabbits (60 total) were reportedly given Zofran doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. In this study, there was a reported increase in the number of intra-uterine deaths in the 4 mg/kg group versus lower- dose groups. The study also reported maternal weight loss in the exposed groups. Developmental retardation in offspring and fetuses were noted – namely, areas of the parietal (body cavity) were not fully ossified, and the hyoid (neck) failed to ossify completely.

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

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

126. 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."

127. 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 prior to the development of Zofran and prior to Zofran being marketed 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.

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

129. By 2000, GSK had received at least thirty-two 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.

130. In many instances, GSK received multiple reports in the same month, the same week and even the same day.

131. For example, on or about September 13, 2000, GSK received three separate reports involving Zofran use and adverse events.

132. For two of those incidents, the impact on the baby was so severe that the baby died.

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

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

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

136. 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];

(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").

137. 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.

138. In other words, as referenced above, 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.

139. 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. There were 608,385 pregnancies between January 2004 and March 31, 2011 examined. 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. The unexposed group was defined as women who did not fill a prescription for ondansetron [Zofran] during the exposure time window. The exposure time window was defined as the first 12-week gestational period.

140. 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.

141. 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

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[2] *See,* http://www.nejm.org/doi/full/10.1056/NEJMoa1211035#t=articleBackground

ventricular septal defect and greater than four-times more likely to have offspring with atrioventricular septal defect.

142. 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. 903,207 births were identified in the study period with 1,368 women filling prescriptions for Zofran during the first trimester. 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.

143. The Andersen Study used a larger data set (thirteen 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 was obtained from the National Prescription Registry.

144. 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.

145. 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. Of the 1,501,434 infant births in the study, 43,658 had malformations classified as major (2.9%).[3]

146. 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.

147. Among the major malformations, 14,872 had cardiovascular defects (34%) and 10,491 had a cardiac septum defect (24%).

148. The Danielsson study reported a statistically significantly elevated risk for cardiovascular defects for mothers taking Zofran versus those who did not.

149. The Danielsson study results reported that the mothers who took Zofran during early pregnancy had a 62% increased risk of the infant being born with a cardiovascular defect.

150. Further, the Danielsson study results reported that 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.

151. Since at least 1992, GSK has had mounting evidence showing that Zofran

[3] *See,* http://www.ncbi.nlm.nih.gov/pubmed/25450422

presents an unreasonable risk of harm to prenatal infants.

152. GSK also had actual knowledge at all times that Zofran readily crossed human placental barriers during pregnancy.

153. GSK also had actual knowledge at all times that the animal studies of Zofran cannot reliably support an assertion that Zofran can be used safely or effectively in pregnant women.

154. Since 1992, GSK has received hundreds of reports of major birth defects ssociated with prenatal Zofran exposure.

155. GSK underreported the hundreds of reports of major birth defects associated with prenatal Zofran exposure that it received to the FDA or any representative body of the United States government.

156. GSK fraudulently also concealed its knowledge from healthcare providers and consumers, and failed to warn of the risk of birth defects.GSK knowingly and willfully, unfairly, deceptively, unlawfully or fraudulently promoted Zofran to physicians and patients specifically for the treatment of Morning Sickness in pregnant women despite knowledge of the risks of major birth defects associated with prenatal Zofran exposure.

157. Federal law governing GSK's drug labeling for Zofran, required it to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." *See* 21 C.F.R. § 201.57(e).

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

159. 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.*

160. 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. at § 201.57(e).

161. GSK has received hundreds of reports of birth defects associated with the non-FDA-approved use of Zofran in pregnant women.

162. In response, GSK failed to disclose the severe adverse events to healthcare providers or expectant mothers, including Ms. Shonkwiler and her prescribing healthcare provider.

163. At all times relevant to the complaint, pursuant to 21 C.F.R. § 314.70(c)(2)(i), pharmaceutical companies were free to strengthen a contraindication, warning, precaution, or adverse reaction without prior approval from the FDA.

164. Despite an ability and obligation to add warnings, precautions and adverse reactions to the product labeling for Zofran without prior approval from the FDA, GSK willfully, knowingly, unfairly and deceptively chose not to do so for the sole purpose of marinating its profits and marketing capabilities.

165. Pursuant 21 C.F.R. § 201.128, where "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."

166. At times relevant to the complaint, GSK violated the express terms of 21 C.F.R. § 201.128.

167. At least as of 1997, 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.

168. 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 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, despite GSK's knowledge that:

> a the safety of Zofran for use in human pregnancy had and has not been established;
> 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.

169. From 1993 to the present, despite mounting evidence of the birth defect risk, GSK's prescribing information for Zofran has included the following 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.

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

171. 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.

172. GSK's inclusion of the phrase "Pregnancy Category B" in Zofran's prescribing information refers to the FDA's pregnancy categorization scheme applicable to prescription drugs in the United States.

173. 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) as follows:

Categories of Risk for Drugs During Pregnancy

CATEGORY	DESCRIPTION
A	These drugs are the safest. Well- designed studies in people show no risks to the fetus.
B	Studies in animals show no risk to the fetus, and no well-designed studies in people have been done. *or* Studies in animals show a risk to the fetus, but well-designed studies in people do not.
C	No adequate studies in animals or people have been done. *or* In animal studies, use of the drug resulted in harm to the fetus, but no information about how the drug affects the human fetus is available.
D	Evidence shows a risk to the human fetus, but benefits of the drug may outweigh risks in certain situations. For example, the mother may have a life-

	threatening disorder or a serious disorder that cannot be treated with safer drugs.
X	Risk to the fetus has been proved to outweigh any possible benefit

174. Zofran is presently listed as an FDA Category B drug.

175. 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 as follows:

> **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.* at § 201.57(f)(6)(i)(e) (emphasis added).

176. Beginning at least in 1992, GSK had positive evidence of human fetal risk posed by Zofran based upon more than 200 reports to GSK of birth defects, as well as epidemiology studies and placental-transfer studies reporting on Zofran's teratogenic risk.

177. At all relevant times, GSK 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.

178. The FDA has 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).[4] T

179. 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."

180. In the years before and during which 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 of it for use in pregnant women. In the years before and during which the 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 warnings accompanying Zofran were inadequate and defective.

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

182. Despite that fact, 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 the State of Colorado.

183. After the FDA approved Zofran in 1991, and despite available evidence showing that Zofran presented an unreasonable risk of harm to prenatal infants exposed to Zofran, 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.

184. 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, which violated the Federal Food Drug and Cosmetic Act and its implementing regulations.

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[4] *See,* http://www.gpo.gov/fdsys/pkg/FR-2014-12-04/html/2014-28241.htm

185. 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).

186. 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.

187. But the promotional labeling failed to present any information regarding the risks associated with use of Zofran.

188. 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."

189. 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.

190. As detailed above, GSK's promotion of Zofran for use in pregnancy eventually led to a federal governmental investigation and related expansive fine and guilty plea.

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

192. Had Plaintiff Stephanie Martinez and/or her healthcare providers known of the increased risk of birth defects associated with Zofran, she would not have taken Zofran during pregnancy and S.M. would not have been born with congenital malformations.

193. As a direct and proximate result of GSK's conduct, S.M. suffered congenital heart defects which caused her death.

FIRST CLAIM FOR RELIEF
(Negligence – Defendant DiMaria)

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

195. At all times material hereto, Defendant DiMaria owed to S.M. the duty to

exercise that degree of skill, knowledge, care, and attention as required of one holding himself out as having special knowledge and skill in the field of emergency medicine.

196. Defendant DiMaria was negligent in his care and treatment of S.M. and that negligence includes, but is not limited to, one or more of the following:

a. Failure to appropriately care and treat for S.M.
b. Failure to appropriately interpret S.M.'s medical studies
c. Failure to properly perform S.M.'s echocardiogram
d. Failure to refer S.M. to specialists with expertise in treating patients that had such symptoms
e. Failure to create an appropriate treatment plan for S.M.

197. As direct result of the negligence of the Defendants as set forth in this Complaint, Plaintiff has suffered and have continued to suffer injuries, damages and losses from the wrongful death of S.M., including, without limitation: any economic losses, including any expenses from the wrongful death S.M., funeral and burial expenses, loss of income, and the value of lost services and benefits that Plaintiff might have reasonably expected to receive from S.M., had she lived; any non-economic losses and injuries, including damages for grief, loss of companionship, impairment of quality of life, inconvenience, pain and suffering, emotional distress, psychological complications and other non-economic losses, past and future. Plaintiff claims damages pursuant to C.R.S. §13-21-203, in an amount to be determined by the trier of fact.

SECOND CLAIM FOR RELIEF
(Negligence – GSK)

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

199. 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.

200. 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.

201. GSK, its agents, servants, and/or employees, failed to exercise ordinary care

and failed to comply with existing standards of care in the following acts and/or omissions:

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

b. marketing Zofran for the treatment of Morning Sickness in pregnant women without testing it determine whether or not Zofran was safe for this use;

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

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

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

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

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

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

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

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

k. failing to provide adequate instructions regarding birth defects including cleft palate and cardiac malformations;

l. failing to accompany Zofran with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Zofran;

m. failing to include a black box warning concerning the birth defects associated with Zofran;

n. failing to issue sufficiently strengthened warnings following the existence

of reasonable evidence associating Zofran use with the increased risk of birth defects;

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

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

202. Despite the fact that GSK knew or should have known that Zofran significantly increased the risk of birth defects, GSK continued and continues to negligently and misleadingly market, manufacture, distribute and/or sell Zofran to consumers, including Plaintiff long after it had actual knowledge of the increased risks of birth defects as referenced herein.

203. 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.

204. GSK's negligence was the proximate cause of S.M.'s injuries and death.

205. Had Plaintiff Stephanie Martinez not taken Zofran, S.M. would not have suffered those injuries and consequently died.

206. As a result of the foregoing acts and omissions, S.M. was caused to suffer serious birth defects that caused her death.

207. As a result of the foregoing acts and omissions, Plaintiff has suffered the injuries, damages and losses from the death of S.M. as more fully described herein.

THIRD CAUSE OF ACTION
(NEGLIGENCE PER SE - GSK)

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

209. 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.

210. 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.

211. 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.

212. 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.

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

214. 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.

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

216. Had Plaintiff Stephanie Martinez not taken Zofran, S.M. would not have suffered the congenital heart defects and died.

217. As a result of the foregoing acts and omissions, S.M. suffered congenital heart defects and died.

218. As a result of the foregoing acts and omissions, Plaintiff has suffered the injuries, damages and losses from the death of S.M. as more fully described herein.

FOURTH CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY-GSK)

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

220. 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.

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

222. 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.

223. 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.

224. As a direct and proximate result of the defective nature of Zofran, S.M. was caused to suffer serious birth defects which caused her death.

225. As a result of the foregoing acts and omissions, Plaintiff has suffered the injuries, damages and losses from the death of S.M. as more fully described herein.

FIFTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION - GSK)

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

227. GSK falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff Stephanie Martinez 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's 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.

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

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

230. 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.

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

232. In reliance upon said representations, Plaintiff's prescriber was induced to prescribe Zofran to her, and Plaintiff Stephanie Martinez was induced to and did use Zofran to treat pregnancy-related nausea.

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

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

235. As a result of the foregoing acts and omissions, S.M. suffered birth defects which caused her death.

236. As a result of the foregoing acts and omissions, Plaintiff Plaintiff has suffered the injuries, damages and losses from the death of S.M. as more fully described herein.

SIXTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

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

238. In representations to Plaintiff's healthcare providers, expectant mothers including Plaintiff, 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's use during pregnancy with birth defects.

239. 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 Stephanie Martinez into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

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

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

242. As a result of the foregoing acts and omissions, S.M. suffered suffer serious birth defects which caused her death.

243. As a result of the foregoing acts and omissions, Plaintiff has suffered the injuries, damages and losses from the death of S.M. as more fully described herein.

SEVENTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

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

245. 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's 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.

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

247. As a result of the foregoing acts and omissions, S.M. suffered serious birth defects which caused her death.

248. As a result of the foregoing acts and omissions, Plaintiff has suffered the

injuries, damages and losses from the death of S.M. as more fully described herein more fully described herein.

EIGHTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY-GSK)

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

250. 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's 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.

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

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

253. 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.

254. 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.

255. As a result of the foregoing acts and omissions, S.M. was caused to suffer serious birth defects causing her death.

256. As a result of the foregoing acts and omissions, Plaintiff has suffered the injuries, damages and losses from the death of S.M. as more fully described herein.

NINTH CAUSE OF ACTION

(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR PARTICULAR USE -GSK)

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

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

259. 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.

260. 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.

TENTH CAUSE OF ACTION
(COLORADO CONSUMER PROTECTION ACT – GSK)

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

262. GSK engaged in trade and commerce within the State of Colorado.

263. GSK's violation of express warranties and misrepresentations constitutes a violation of the Colorado Consumer Protection Act. GSK's failure to perform and fulfill its promises, representations, and obligations under the product's warranties constitutes an actionable violation.

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

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

266. GSK failed to provide accurate disclosures of all material information before Plaintiff and her providers transacted to use GSK's product.

267. GSK's willful/knowing withholding of important safety information and critical product information constitutes a violation of the Colorado Consumer Protection Act GSK actively, knowingly, and deceptively concealed its knowledge of its product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

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

269. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally they were unethical and unscrupulous, and caused substantial injury to consumers. GSK engaged in an unconscionable course of action.

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

271. GSK is liable to Plaintiff for all statutory, direct and consequential damages, and fees and costs, resulting from this breach, including multiple damages. been deprived of the society, love, affection, companionship, care and services, of her child, S.M., and is entitled to recovery for said loss.

WHEREFORE, Plaintiff prays that judgment be entered in his favor and against Defendants for general and special damages in an amount which will fully and fairly compensate them for their injuries and damages both past and future. Plaintiff further prays that the court award prejudgment and post judgment interest as permitted by Colorado law, costs of this suit, expert witness fees, and for such other and further relief as this court may deem just and proper.

Dated this 14th day of August 2015.

SCHOENWALD & THOMPSON, LLC

Duly signed original maintained at
Schoenwald & Thompson LLC

/s/ Julia T. Thompson
Julia T. Thompson, # 25897
Attorneys for Plaintiff

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