

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION**

**PATRICK D. REGAN,
VALERIE C. REGAN,
ELIZABETH VAUGHAN ON BEHALF OF THE
BANKRUPTCY ESTATE *IN RE PATRICK D.
REGAN AND VALERIE M. REGAN*, and
PATRICK REGAN ON BEHALF OF THE ESTATE
OF MOLLY REGAN, DECEASED,**

Plaintiffs,

Case No.: 3:15-cv-1166

Judge:

**COMPLAINT
WITH JURY DEMAND**

v.

GLAXOSMITHKLINE LLC,

Defendant.

Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased, complaining against Defendant GlaxoSmithKline LLC, aver and state:

I.) NATURE OF THE ACTION

1. This is an action for injuries suffered by Mr. Regan, Mrs. Regan, and Molly Regan and caused by the drug Zofran, which Defendant GlaxoSmithKline LLC designed, created, manufactured, promoted, marketed, and sold.
2. Specifically, GlaxoSmithKline promoted Zofran off-label, against FDA orders, and illegally as a safe and effective treatment for nausea associated with pregnancy.
3. Based on GlaxoSmithKline's off-label promotion of Zofran as a safe solution for pregnancy-related nausea, Mrs. Regan took Zofran while pregnant.
4. Zofran causes birth defects when taken during pregnancy.

5. Molly Regan was born with heart defects.
6. Molly Regan died as a result of the defects and injuries caused by Zofran.
7. Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased allege Defendant GlaxoSmithKline LLC is liable for the harms Zofran caused because, among other things:
 - a.) GlaxoSmithKline created, designed, and marketed Zofran as a safe and effective solution for nausea during pregnancy;
 - b.) GlaxoSmithKline's promotion of Zofran as a solution for pregnancy-related nausea was an illegal and off-label act;
 - c.) GlaxoSmithKline knew or should have known Zofran was dangerous when taken during pregnancy;
 - d.) GlaxoSmithKline knew or should have known Zofran could cause birth defects when taken during pregnancy;
 - e.) Zofran was unreasonably dangerous due to design defects, manufacturing defects, and insufficient warnings and that these dangers caused great harm to Molly Regan;
 - f.) Safer alternatives to Zofran existed and were known and available to GlaxoSmithKline, but GlaxoSmithKline chose nonetheless to promote Zofran as a solution to pregnancy-related nausea;
 - g.) GlaxoSmithKline misled the Regans, the Regans' physician, the medical community, the public in general, and regulators about Zofran; and,
 - h.) GlaxoSmithKline created express and implied warranties regarding Zofran and breached those.

8. Plaintiffs allege they suffered damages as a result.

II.) PARTIES

9. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

10. Plaintiff Valerie C. Regan is an individual, is a resident of Toledo, Ohio, and is a citizen of Ohio.

11. Plaintiff Patrick D. Regan is an individual, is a resident of Toledo, Ohio, and is a citizen of Ohio.

12. Plaintiff Elizabeth Vaughan on behalf of the bankruptcy estate of *In re Patrick D. Regan and Valerie M. Regan* is a bankruptcy estate created in The Northern District of Ohio.

13. Plaintiff the Estate of Molly Regan is an estate created under the laws of the State of Ohio represented by its personal representative, Patrick Regan.

14. Defendant GlaxoSmithKline LLC is a limited liability company organized under the laws of Delaware.

15. GlaxoSmithKline LLC's sole member is GlaxoSmithKline Holdings (Americas) Inc. GlaxoSmithKline Holdings (Americas) Inc. is a Delaware corporation with its headquarters and principal place of business in Delaware.

16. Therefore, Defendant GlaxoSmithKline LLC is a citizen of Delaware.

17. GlaxoSmithKline engaged in the business of designing, licensing, manufacturing, testing, advertising, warranting, distributing, supplying, and selling Zofran as well as introducing Zofran into the stream of commerce in Ohio and across the United States.

III.) JURISDICTION AND VENUE

18. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

19. This suit involves birth defects caused to a minor child and the resulting costs and emotional damage; the amount in controversy exceeds \$75,000, exclusive of interest and costs.

20. Complete diversity exists between Plaintiffs and Defendant and the amount in controversy exceeds the jurisdictional threshold, so this Court has jurisdiction. 28 U.S.C. § 1332.

21. GlaxoSmithKline and its affiliated companies have a presence in this district and marketed their products in this district, including direct-to-consumer marketing, communication with and marketing to physicians, and sale of many of its other products in this district. Therefore, venue is proper in this district under 28 U.S.C. § 1391(b)(1) and 1391(d).

IV.) COMMON FACTS

22. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

a.) Background

23. GlaxoSmithKline first obtained FDA approval for Zofran in 1991 and introduced it to the market thereafter.

24. Initially, Zofran was indicated only for treating nausea and vomiting caused by chemotherapy.

25. GlaxoSmithKline later sought and obtained FDA approval to add a second indication: treatment of postoperative nausea and vomiting.

b.) Zofran's Pregnancy Warnings

26. GlaxoSmithKline classified Zofran's Teratogenic Effects (that is, the likelihood of the drug to cause birth defects) as "Category B." For example:

8.1 Pregnancy

Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at intravenous doses up to 4 mg/kg per day (approximately 1.4 and 2.9 times the recommended human intravenous dose of 0.15 mg/kg given three times a day, respectively, based on body surface area) 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.

Zofran Label, September 2014 update.

27. But GlaxoSmithKline had not done any studies of pregnancy risks prior to introducing Zofran.

28. Furthermore, GlaxoSmithKline claims it studied the question of whether Zofran is teratogenic later and concluded it is not. But, the study on which it relies has been questioned in the scientific community.

c.) Off-Label Promotion

29. At no time has Zofran ever been approved for the treatment of pregnancy-related nausea and vomiting.

30. Several governmental agencies, including HHS-OIG (Health and Human Services, Office of the Inspector General), the FDA, and the FBI, conducted an investigation of GlaxoSmithKline's drug promotion practices related to its drugs Avandia, Paxil, Wellbutrin, and Zofran.

31. The investigation led to the government bringing civil and criminal charges against GlaxoSmithKline.

32. The DOJ described the allegations:

Zofran: During the period January 1, 2002 through December 31, 2003, 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 caused purchases by Medicaid and the other Federal Health Care Programs.

Settlement Agreement, (<http://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/off-label-agreement.pdf>).

33. In 2012, GlaxoSmithKline opted to enter a settlement agreement that the United States Department of Justice called “the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.” (<http://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>).

34. The settlement included GlaxoSmithKline’s “alleged conduct [of] promoting . . . Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs.” (*Id.*)

35. GlaxoSmithKline negotiated the right to deny the facts and liability surrounding the settlement agreement, but paid \$3 billion to resolve these claims (including claims for similar conduct related to drugs other than Zofran).

36. Even though the DOJ's settlement agreement covered only a limited period of conduct, on information and belief, GlaxoSmithKline promoted Zofran off-label in this—or a similar—fashion before 2002 and after 2003.

d.) Zofran's Teratogenicity

37. As GlaxoSmithKline's promotion efforts paid off, more pregnant women used Zofran and this led to an increasing number of adverse events.

38. By 2000, dozens of physician reports began to show a high rate of teratogenicity, with Zofran use being associated with congenital heart defects, kidney malformations, and cleft palate and other facial defects. Furthermore, data were showing intrauterine deaths, still births, deaths shortly after births, and serious congenital defects in children who survived.

39. Citing the high number of Zofran prescriptions written to pregnant women (no doubt as an effect of GlaxoSmithKline's off-label promotion), in 2004, a group of researchers undertook a small study to determine if Zofran was a Teratogen.

40. The study showed twice the rate of "Major malformation" (3.5% as opposed to 1.8%) but could not call that change statistically significant because of the small sample size of only 176. Einarson, *et al.*, THE SAFETY OF ONDANSETRON FOR NAUSEA AND VOMITING OF PREGNANCY: A PROSPECTIVE COMPARATIVE STUDY, *BJOG: An International Journal of Obstetrics & Gynaecology*, Volume 111, Issue 9, pages 940–943, September 2004.

41. Rather than commission a larger study, GlaxoSmithKline ignored the Einarson study's danger signs and continued to promote Zofran without warning of its true teratogenicity.

42. In 2011, a group of researchers undertook the task of studying whether nausea and vomiting during pregnancy were themselves associated with certain birth defects. Anderka, *et al.* MEDICATIONS USED TO TREAT NAUSEA AND VOMITING OF PREGNANCY AND THE RISK OF

SELECTED BIRTH DEFECTS. BIRTH DEFECTS RESEARCH. Part A, Clinical and Molecular Teratology 94.1 (2012): 22–30. PMC.

43. The Anderka study found no association between nausea and vomiting and birth defects, but found a correlation between certain birth defects and Zofran that “warrant further investigation.”

44. On information and belief, GlaxoSmithKline has commissioned no study to further investigate the link found in the Anderka study.

45. In the last several years, additional studies have shown more clearly what the early data evidenced: a link between Zofran and certain birth defects, particularly cleft palate, heart defects, intrauterine death, and other malformations.

46. For example, in 2014, a study was released showing Zofran causes a twofold relative risk for certain cardiac defects: “The risks for a cardiovascular defect and notably a cardiac septum defect were increased and statistically significant (OR=1.62, 95% CI 1.04-2.14, and RR 2.05, 95% CI 1.19-3.28, respective).” *Danielsson, et al.* USE OF ONDANSETRON DURING PREGNANCY AND CONGENITAL MALFORMATIONS IN THE INFANT. *Reproductive Toxicology* (2014).

47. Nevertheless, GlaxoSmithKline maintains its position that it is unaware of any link and continues to refuse to update the Zofran label.

V.) CASE-SPECIFIC FACTS

48. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

49. When pregnant with her first child, Plaintiff Valerie Regan presented to her physician with symptoms of morning sickness (that is, nausea related to pregnancy).

50. Ms. Regan's physician prescribed the drug that Defendant had marketed and detailed as a safe and effective solution for pregnancy-related nausea and vomiting: Zofran.
51. Ms. Regan took Zofran as prescribed for the relief of morning sickness.
52. Ms. Regan's pregnancy was otherwise unremarkable until nine days before delivery when the baby's heart rate began to decelerate.
53. Molly Margaret Regan was born March 17, 2006.
54. Immediately, physicians diagnosed Molly as having a right ventricular heart defect and kept her in the ICU.
55. At three days old, Molly Regan crashed and physicians could not revive her.
56. Molly Margaret Regan died on March 20, 2006.
57. Mr. and Mrs. Regan have since devoted their time and money to bringing awareness and understanding to heart defects like Molly's.

VI.) DISCOVERY RULE AND TOLLING ALLEGATIONS

58. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:
59. The claims described herein are brought within the statutory period because claims involving minors are tolled until the age of majority in many applicable jurisdictions.
60. Furthermore, GlaxoSmithKline actively concealed information and actively misled the Regans, their physician, the medical community in general, the public at large, and federal regulators regarding Zofran's propensity to cause birth defects and its appropriateness for use by pregnant mothers.
61. GlaxoSmithKline actively concealed the cause of Molly Regan's birth defects.

62. GlaxoSmithKline has refused—and continues to refuse—to provide the Regans, their physician, the medical community in general, the public at large, and federal regulators with true and accurate information about Zofran, about the risks Zofran presents, and about the injuries Zofran caused.

63. Because of GlaxoSmithKline's concealment of and misrepresentations regarding Zofran's true risks and the injuries Zofran caused, the Regans could not have reasonably discovered GlaxoSmithKline's wrongdoing or Zofran's role in causing Molly Regan's injuries at any time prior to the commencement of this action.

64. As alleged herein, GlaxoSmithKline's fraudulent misrepresentations, fraudulent omissions, reckless misrepresentations, reckless omissions, negligent misrepresentations, and negligent omissions tolled the running of any statute of limitations.

65. Where applicable, the discovery rule should be applied to toll the running of the statute of limitations until the Regans knew, or, through the exercise of reasonable care and diligence should have known, of facts indicating that Molly Regan had been injured, the cause of the injuries, the nature of Zofran's dangers and defects, and GlaxoSmithKline's tortious wrongdoing.

66. Despite diligent investigation by the Regans, they did not know the cause of Molly Regan's injuries, the nature of the defective pharmaceutical, or the tortious nature of GlaxoSmithKline's wrongdoing until a date within the applicable statute of limitations for filing their claims. Therefore, under the appropriate application of the discovery rule, the Regans filed this suit within the applicable statute of limitations period.

67. The running of the statute of limitations in this case should also be tolled due to equitable tolling. GlaxoSmithKline is estopped from asserting a statute of limitations defense due to its fraudulent concealment, through affirmative misrepresentations made to the Regans and their

physicians and through omissions withheld from the Regans and their physicians. As a result of GlaxoSmithKline's fraudulent misrepresentations and fraudulent concealment, the Regans and their physicians were unaware and could not have known or learned through reasonable diligence that they had been exposed to the risks alleged herein and that those risks were the direct, proximate result of GlaxoSmithKline's wrongful acts and omissions.

68. The Regans assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitation, including equitable tolling, estoppel, delayed discovery, the discovery rule, and fraudulent concealment.

69. Therefore, the Regans timely filed this action.

VII.) CAUSES OF ACTION

COUNT I **FAILURE TO WARN**

70. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

71. GlaxoSmithKline failed to properly label Zofran, marketed Zofran beyond its approved indications, and failed to warn the Regans and their physicians of Zofran's dangers.

72. GlaxoSmithKline knew of multiple dangers with Zofran, including its likelihood to cause birth defects.

73. GlaxoSmithKline did not adequately warn the Regans and their physicians of these and other dangers.

74. GlaxoSmithKline's failure to warn left the Regans incapable of making informed choices and granting informed consent.

75. Had the Regans or their physicians known of Zofran's potential for causing deleterious, permanent harm to Molly Regan, they would not have used Zofran for pregnancy-related nausea.

76. GlaxoSmithKline's inadequate warnings were negligent and caused deleterious, permanent harm to Molly Regan.

77. Furthermore, GlaxoSmithKline is strictly liable for injuries resulting from their failure to warn.

78. Furthermore, GlaxoSmithKline is liable under Ohio's Products Liability Act, R.C. §§ 2307.71–2307.80, for failing to warn.

79. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT II **DESIGN DEFECT**

80. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

81. GlaxoSmithKline is a "Manufacturer" in that it designed, produced, made, and fabricated Zofran and introduced the pharmaceutical into the stream of commerce.

82. GlaxoSmithKline had a duty to design, manufacture, test, market, advertise, label, distribute, and sell Zofran so that it was reasonably safe for its foreseeable use.

83. The Regans's use of Zofran for nausea and vomiting associated with pregnancy was not only anticipated by GlaxoSmithKline, but, in fact, was precisely solicited by GlaxoSmithKline.

84. Due to design defects, Zofran is unreasonably dangerous in that:
- a.) it causes heart defects in developing fetuses;
 - b.) it causes cleft palate and other facial defects and deformities in developing fetuses;
 - c.) it causes in utero death;
 - d.) it causes still birth; and,
 - e.) it causes other birth defects in developing fetuses.
85. Zofran's design defects caused Molly Regan's injuries and there is no other reasonable, secondary cause of her injuries.
86. Zofran's design is defective in that, when it left GlaxoSmithKline's control, it was more dangerous than an ordinary consumer would expect when used in the manner in which GlaxoSmithKline intended Zofran to be used, when used in the manner GlaxoSmithKline promoted (i.e. for relief of pregnancy-related nausea and vomiting), or when used in a reasonably foreseeable manner.
87. Zofran's design is defective in that, when it left GlaxoSmithKline's control, its known, knowable, and/or foreseeable risks outweighed any potential benefit it might provide.
88. Zofran's design is defective in that, when it left GlaxoSmithKline's control, it was more dangerous than necessary, particularly to pregnant women.
89. Zofran's dangers are so great that reasonable health care professionals—including the Regans's physician—would not prescribe its use if they knew of Zofran's true nature.
90. Zofran's dangers are so great that reasonable consumers in general and the Regans in specific would not have allowed its use if they knew of Zofran's true nature and likelihood to cause birth defects and death.

91. GlaxoSmithKline knew or should have known of Zofran's dangers; knew or should have known of safer alternatives to Zofran; and disregarded the risks to Molly Regan and other children whose mothers took Zofran while pregnant.

92. GlaxoSmithKline is negligent and is grossly negligent in causing harm to Molly Regan.

93. Notwithstanding that, GlaxoSmithKline is strictly liable for Zofran's design defects and the injuries they caused.

94. Furthermore, GlaxoSmithKline is liable under Ohio's Products Liability Act, R.C. §§ 2307.71–2307.80, for injuries resulting from these design defects.

95. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT III
GROSS NEGLIGENCE

96. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

97. GlaxoSmithKline owed Plaintiffs and all consumers a duty of reasonable care in how it designed Zofran, warned of Zofran's dangers, and promoted, marketed, detailed, and sold Zofran.

98. GlaxoSmithKline breached their duty of care as alleged herein.

99. In failing to properly warn consumers and physicians of Zofran's propensity to cause birth defects, GlaxoSmithKline consciously and voluntarily disregarded the risks to Molly Regan and consumers in general.

100. Furthermore, in promoting Zofran as a safe and effective remedy for nausea and vomiting associated with pregnancy, GlaxoSmithKline consciously and voluntarily disregarded the risks to Molly Regan and consumers in general.

101. GlaxoSmithKline knew Zofran was dangerous when taken by pregnant women, yet chose not to warn the Regans, their physicians, the medical community, or the public.

102. GlaxoSmithKline knew it had not obtained regulatory approval to promote Zofran for pregnancy-related nausea and vomiting yet did so nonetheless.

103. GlaxoSmithKline knew Zofran presented danger to patients, particularly those who were pregnant but marketed and sold the drug nonetheless.

104. GlaxoSmithKline knew Zofran was associated with an increasing number of birth-defect-related adverse events but concealed those or failed to act on those with follow-up study.

105. These breaches of duties were wanton and willful and demonstrate blatant, callous, and indifferent conduct towards Plaintiffs and consumers in general.

106. GlaxoSmithKline is liable under Ohio's Products Liability Act, R.C. §§ 2307.71–2307.80, for injuries resulting from this gross negligence.

107. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline

LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT IV
NEGLIGENCE

108. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

109. GlaxoSmithKline owed Plaintiffs and all consumers a duty of reasonable care in how it designed Zofran, warned of Zofran's dangers, and promoted, marketed, detailed, and sold Zofran.

110. As previously alleged under strict the liability sections, the gross negligence section, and throughout the Complaint, GlaxoSmithKline breached the duty of care and was negligent in:

- a.) how it designed Zofran;
- b.) how it failed to warn of Zofran's dangers; and,
- c.) how it actively marketed Zofran as a remedy for pregnancy-related nausea and vomiting.

111. A reasonable manufacturer should have known:

- a.) that Zofran's risks were unreasonably greater than necessary and/or than other similar products and that these enhanced risks put Molly Regan and other patients in danger;
- b.) that it had failed to warn the Regans and other expecting mothers of Zofran's risks;
- c.) that it had falsely promoted Zofran off-label as a remedy for pregnancy-related nausea and vomiting;

d.) that a growing number of birth-defect-related adverse events should have been properly investigated to ascertain Zofran's risks; and,

e.) that these breaches of duties put infants, such as Molly Regan at risk of birth defects.

112. The dangers presented by GlaxoSmithKline's breaches are so great that reasonable health care professionals—including the Regans's physicians—would not prescribe Zofran's use if they knew the extent of even one of these breaches

113. The dangers presented by GlaxoSmithKline's various breaches are so great that reasonable consumers—including the Regans—would not have taken Zofran if they knew of even one of these breaches.

114. GlaxoSmithKline is liable under Ohio's Products Liability Act, R.C. §§ 2307.71–2307.80, for injuries resulting from this negligence. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT V
FRAUDULENT PROMOTION

115. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

116. Through its marketing, sales, and detailing representatives, GlaxoSmithKline promoted Zofran off-label as a safe and effective treatment for pregnancy-related nausea and vomiting.

117. A pharmaceutical manufacturer has a duty to promote its products only for FDA-approved indications, which pregnancy-related nausea and vomiting were not.

118. GlaxoSmithKline broke the law by promoting Zofran off-label and settled the criminal accusations with the United States (albeit without an express statement of guilt).

119. GlaxoSmithKline's promotion of Zofran as a safe and effective treatment for pregnancy-related nausea and vomiting is fraud.

120. Had the Regans known of Zofran's potential for causing deleterious, permanent harm to Molly Regan, of the fact that GlaxoSmithKline promoted Zofran off-label and illegally, and of GlaxoSmithKline's failure to act on a growing body of scientific evidence of Zofran's teratogenicity, they would not have taken Zofran.

121. GlaxoSmithKline is liable for the harms caused by illegal off-label promotion.

122. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT VI
FRAUD BY CONCEALMENT

123. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

124. GlaxoSmithKline had a duty to disclose certain concealed facts, which include the true risks and dangers posed by Zofran, the adverse events resulting from Zofran, and the need for further study of Zofran's propensity to cause birth defects.

125. Furthermore, GlaxoSmithKline cemented its duty to provide the Regans and other Zofran recipients with disclosures by choosing to disclose certain limited contraindications while concealing the other grave dangers that form the basis of this suit.

126. GlaxoSmithKline's partial disclosure created a duty to fully disclose all Zofran's dangers to avoid misleading the Regans, their physicians, the medical community, and the public.

127. The dangers presented by GlaxoSmithKline's various breaches are so great that reasonable consumers—including the Regans—would not have taken Zofran if they knew the information GlaxoSmithKline fraudulently concealed.

128. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT VII
FRAUDULENT MISREPRESENTATION

129. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

130. GlaxoSmithKline had a duty to accurately represent certain material facts, which include those dangers of which it knew.

131. Through its silence and through its statements, GlaxoSmithKline actively misrepresented Zofran's safety to the Regans, their physicians, the medical community, and the public.

132. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT VIII
NEGLIGENT MISREPRESENTATION

133. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

134. GlaxoSmithKline had a duty to accurately represent certain material facts, which include those dangers of which it knew.

135. GlaxoSmithKline duty to make accurate representations to the Regans, their physicians, the medical community, and the public existed when it first brought Zofran to market and continue on through this day.

136. For the reasons detailed throughout, GlaxoSmithKline was—and continues to be—negligent in its representations to the Regans, their physicians, the medical community, and the public.

137. The dangers presented by GlaxoSmithKline's various breaches are so great that reasonable consumers—including the Regans—would not have taken Zofran if they knew the information GlaxoSmithKline fraudulently concealed.

138. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT IX
BREACH OF EXPRESS WARRANTY

139. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

140. GlaxoSmithKline made express warranties to the Regans and their physicians when it promoted Zofran off-label as a safe and effective treatment for pregnancy-related nausea and vomiting.

141. In particular, GlaxoSmithKline warranted at least the following:

- a.) that Zofran was safe for use in pregnant women;
- b.) that Zofran was effective for nausea and vomiting related to pregnancy;
- c.) that it was operating within the law and regulatory approval in promoting the drug to this population; and,
- d.) that it was active in monitoring Zofran's dangers and following up on early indications the drug may be teratogenic.

142. GlaxoSmithKline breached each of these warranties.

143. Not knowing GlaxoSmithKline was making false warranties and breaching those, the Regans and their physicians relied on GlaxoSmithKline's warranties when deciding to use Zofran for pregnancy-related nausea and vomiting.

144. The Regans would not have used Zofran while pregnant—and their physicians would not have prescribed Zofran for pregnancy-related nausea and vomiting—if they knew GlaxoSmithKline breached these warranties it made about Zofran.

145. GlaxoSmithKline breached express warranties it made regarding Zofran and is liable for those breaches.

146. Furthermore, GlaxoSmithKline is liable under Ohio's Products Liability Act, R.C. §§ 2307.71–2307.80, for injuries resulting from Zofran not conforming to its representations.

147. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT X
BREACH OF IMPLIED WARRANTY

148. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

149. By introducing Zofran into the stream of commerce and by promoting it as a safe and effective treatment for pregnancy-related nausea and vomiting, GlaxoSmithKline impliedly warranted the product was merchantable, including: that Zofran would pass without objection in

the trade; that Zofran would be of average quality; that it would be fit for its ordinary purpose and use; that it would be packaged and labeled properly; and that it would conform to the promises made in the marketing, packaging, and labeling of the product.

150. Zofran is dangerous as alleged herein, is less effective than promised, is not of average quality, is not fit for its ordinary purpose—including the purpose GlaxoSmithKline promoted it for—, was not labeled in a way to warn the Regans or their physicians of its grave dangers, and did not conform to its marketing, packaging, and labeling promises of being safe for use while pregnant.

151. Therefore, Zofran is not merchantable and GlaxoSmithKline breached this warranty.

152. At the time it distributed Zofran and promoted Zofran off-label, GlaxoSmithKline knew or should have known Zofran was not merchantable.

153. The Regans and their physicians relied on GlaxoSmithKline's implied warranties when deciding to take Zofran for pregnancy-related nausea and vomiting.

154. The Regans would not have used Zofran while pregnant—and their physicians would not have prescribed Zofran for pregnancy-related nausea and vomiting—if they knew GlaxoSmithKline breached these warranties it made about Zofran.

155. GlaxoSmithKline breached implied warranties made regarding Zofran and is liable for those breaches.

156. Furthermore, GlaxoSmithKline is liable under Ohio's Products Liability Act, R.C. §§ 2307.71–2307.80, for injuries resulting from Zofran not conforming to its representations.

157. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT XI
INFLICTION OF EMOTIONAL DISTRESS

158. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

159. GlaxoSmithKline acted in an extreme and outrageous manner in a variety of ways, including:

- a.) by illegally promoting Zofran off-label as a safe and effective treatment for pregnancy-related nausea and vomiting;
- b.) by concealing and ignoring Zofran's risks and failing to warn of those risks;
- c.) by failing to conduct more research when scientific data and adverse events began to indicate a correlation between Zofran and birth defects; and,
- d.) by other conduct as detailed throughout this Complaint.

160. GlaxoSmithKline should have known and/or did know its conduct could cause and likely would cause emotional distress in parents whose children died or developed birth defects as a result of Zofran.

161. As a direct and proximate result of GlaxoSmithKline's wrongful actions, Molly Regan died from the serious medical conditions—including heart defects—caused by Zofran.

162. These conditions have directly caused emotional distress in the Regans.

163. GlaxoSmithKline intentionally caused, or recklessly disregarded the risks of causing, this emotional distress.

164. Alternatively, GlaxoSmithKline was negligent in causing Plaintiffs' emotional distress.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT XII **LOSS OF CONSORTIUM**

165. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

166. GlaxoSmithKline's wrongful actions caused Molly Regan's heart defects and death.

167. These diminished and deprived—and will continue to diminish and deprive—Molly Regan's parents (the Regans) of Molly Regan's services, companionship, and society.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand judgment against Defendant GlaxoSmithKline LLC for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT XIII **OHIO STATUTORY AND COMMON LAW REMEDIES**

168. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

169. By reference, Plaintiffs plead violations of Ohio state statutory and common law remedies where Ohio has adopted state statutory or common law remedies to replace the common law theories espoused in the Counts above and the Punitive Damages Allegations below.

PUNITIVE DAMAGES ALLEGATIONS

170. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

171. GlaxoSmithKline's acts, conduct, and omissions, as alleged throughout this Complaint, were willful and malicious.

172. GlaxoSmithKline, through its officers, directors, managers, and agents actively, willfully, and knowingly promoted Zofran off-label and illegally as a safe and effective treatment for pregnancy-related nausea and vomiting.

173. GlaxoSmithKline, through its officers, directors, managers, and agents, knew Zofran was dangerous and presented a substantial and unreasonable risk of harm to Molly Regan but hid this and pushed forward with Zofran promotion and sales.

174. GlaxoSmithKline committed these acts with a conscious disregard for Mr. Regan, Mrs. Regan, and Molly Regan's rights and well-being.

175. GlaxoSmithKline committed these acts for the primary purpose of increasing profits from Zofran sales.

176. GlaxoSmithKline's outrageous and unconscionable conduct warrants an award of exemplary and punitive damages in an amount appropriate to punish and make an example of it.

177. GlaxoSmithKline's conduct was so despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by

GlaxoSmithKline with willful and conscious disregard for the safety of Molly Regan, entitling Plaintiffs to punitive and exemplary damages.

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased demand an award of punitive damages against Defendant GlaxoSmithKline LLC.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Patrick D. Regan, Valerie C. Regan, Elizabeth Vaughan on behalf of the bankruptcy estate *In re Patrick D. Regan and Valerie M. Regan*, and Patrick Regan on behalf of the Estate of Molly Regan, deceased pray for the following judgment against Defendant GlaxoSmithKline LLC, as appropriate to each cause of action alleged:

- A. General damages in an amount that will conform to proof at time of trial;
- B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;
- C. Loss of earnings and impaired earning capacity according to proof at the time of trial;
- D. Medical expenses, past and future, according to proof at the time of trial;
- E. Past and future mental and emotional distress, according to proof;
- F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;
- G. Punitive or exemplary damages according to proof;
- H. Restitution, disgorgement of profits, and other equitable relief;
- I. Injunctive relief;
- J. Attorneys' fees;

- K. Costs of suit incurred herein;
- L. Pre-judgment interest as provided by law; and
- M. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands a jury trial on all claims so triable in this action.

June 10, 2015.

Respectfully Submitted,

/s/ James G. O'Brien

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