IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

CORY COX AND JILL COX, EACH INDIVIDUALLY and ON BEHALF OF JACOB COX, THEIR MINOR CHILD **PLAINTIFFS**

VS. **CASE NO.** 4:15CV284-BRW

This case assigned to District Judge Wilson
and to Magistrate Judge Kearney

GLAXOSMITHKLINE, LLC, A LIMITED LIABILITY COMPANY, GLAXOSMITHKLINE HOLDINGS, (AMERICAS) INC., GLAXO, INC., and GLAXO WELLCOME, INC. **DEFENDANTS**

COMPLAINT

JURISDICTION AND VENUE

1. The United States District Court for the Eastern District of Arkansas has jurisdiction of this case and the parties hereto because of the fact the prayer for damages is in excess of $75,000, and the Plaintiffs are residents of the state of Arkansas and the Defendants are non-residents of the state of Arkansas, thereby allowing diversity of citizenship and all other allegations for the filing of the Complaint in federal court.

2. The venue for this case is in the United States District Court for the Eastern District of Arkansas, by reason of the fact that the Complaint involves facts that arose in Pulaski County, Arkansas.

PARTIES

3. Cory Cox is the husband of Jill Cox and the father of Jacob Cox.

Cory Cox brings this action on behalf of Jacob Cox, his minor child. Cory Cox resides at 112 Corondelet Lane, Maumelle, AR 72113.

4. Jill Cox is the wife of Cory Cox and the mother of Jacob Cox. She was prescribed Zofran during the early stages of her pregnancy for the treatment of morning sickness. This is alleged to have caused Jacob Cox's birth defects. Jill Cox brings this action on behalf of Jacob Cox, her minor child. Jill Cox resides at 112 Corondelet Lane, Maumelle, AR 72113.

5. Jacob Cox is a minor who sustained personal injuries and damages as a result of birth defects and other problems associated with the taking of Zofran. He was born on June 1, 2012 with a partial cleft lip. Approximately three months after he was born, he had surgery to repair his lip, and has a scar from the surgery. Jacob Cox resides at 112 Corondelet Lane, Maumelle, AR 72113.

6. GlaxoSmithKline ("GSK") is a limited liability company organized under the laws of the State of Delaware. GSK's sole member is GlaxoSmithKline Holdings, (Americas) Inc., which is a Delaware corporation, and which has identified its principal place of business in Wilmington, Delaware. GSK is the successor in interest to Glaxo, Inc. and Glaxo Wellcome, Inc. Glaxo, Inc. sponsored the original New Drug Application for Zofran. Glaxo, Inc., through its division Cerenex Pharmaceuticals, authored the original package

insert and labeling for Zofran, including warnings and precautions attendant to its use. Glaxo Wellcome, Inc. sponsored additional New Drug Applications for Zofran, monitored and evaluated post-market adverse event reports arising from the use of Zofran, and authored product labeling for Zofran. The term GSK refers to GlaxoSmithKline, its predecessors Glaxo, Inc. and Glaxo Wellcome, Inc., and other GSK predecessors and/or affiliates that discovery reveals were involved in the testing, development, manufacture, marketing, sale, and/or distribution of Zofran.

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

FACTUAL BACKGROUND AND ALLEGATIONS COMMON TO ALL COUNTS

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

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

10. For GSK to market Zofran lawfully for the treatment of morning

sickness in pregnant women, it must first adequately test the drug and formally submit to the FDA as evidence demonstrating that the drug is safe and effective for the treatment of morning sickness.

11. GSK did not submit to the FDA any data demonstrating the safety or efficacy of Zofran for treating morning sickness in pregnant women.

12. Around September of 2011, Jill Cox was prescribed Zofran early in the first trimester of her pregnancy. She was prescribed Zofran because GSK promoted the drug as a way to prevent morning sickness. Jill Cox took the prescribed Zofran during the first trimester of her pregnancy.

13. On June 1, 2012, Jacob Cox was born with a partial cleft lip. There is no history of a cleft lip birth defect in Jacob Cox's family.

14. Approximately three months later, Jacob Cox underwent corrective surgery at the Arkansas Childrens' Hospital to repair his lip. He suffered a permanent scar from the repair that is often red and inflamed. The bottom of his lip is not symmetrical.

15. Besides corrective surgery from his cleft lip, Jacob Cox has also had developmental delays from the sedations. It took him longer to speak and walk than the average infant, and he has visited a speech therapist, a developmental therapist, and a physical therapist. These therapist visits are unduly burdensome on the Cox family.

16. Plaintiff Jill Cox was unaware of the danger of Zofran or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during pregnancy. Likewise, Plaintiff Cory Cox was unaware of these facts.

17. Had Plaintiff Jill Cox 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 Jacob Cox would not have been born with a congenital malformation.

18. As a direct and proximate result of GSK's conduct, Plaintiffs have all suffered and incurred harm including severe and permanent emotional and physical pain and suffering, mental anguish, medical expenses and other economic and noneconomic damages, and will require more constant and continuous medical monitoring and treatment than had they not been exposed to Zofran.

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

20. In the United States and Arkansas, 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.

21. Plaintiffs file this lawsuit within the applicable statute of limitations period, filing upon first reason to learn and discover that Zofran caused the appreciable harm sustained by their son, Jacob Cox.

COUNT I
NEGLIGENCE- FAILURE TO EXERCISE REASONABLE CARE

22. As a cause of action and ground for relief, plaintiff alleges the factual matters described in paragraphs No. 1 through 21, inclusive, of the complaint as a part of this count.

23. 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.

24. 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.

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

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

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

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

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

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

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

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

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

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

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

(k) Failing to provide adequate instructions regarding birth defects including cleft palate and cardiac malformations;

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

(m) Failing to include a black box warning concerning the birth defects associated with Zofran;

(n) Failing to issue sufficiently strengthened warnings following the existence of reasonable evidence associating Zofran use with the increased risk of birth defects;

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

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

26. 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 Jill Cox.

27. GSK's negligence was the proximate cause of Plaintiffs' injuries, harm and economic loss, collectively and individually, which Plaintiffs suffered and/or will continue to suffer, as individuals and as a family.

COUNT II
NEGLIGENCE PER SE

28. As a cause of action and ground for relief, plaintiff alleges the factual matters described in paragraphs No. 1 through 27, inclusive, of the complaint as a part of this count.

29. 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.

30. 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.

31. 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.

32. The laws violated by GSK were designed to protect Plaintiffs, as consumers and individuals, 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.

33. 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 Plaintiffs.

34. GSK's negligence was the proximate cause of Plaintiffs' injuries,

harm and economic loss, which Plaintiffs suffered and/or will continue to suffer, each individually and as a family.

COUNT III
PRODUCTS LIABILITY

35. As a cause of action and ground for relief, plaintiff alleges the factual matters described in paragraphs No. 1 through 34, inclusive, of the complaint as a part of this count.

36. 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.

37. GSK failed to provide adequate warnings to physicians and users,

including Plaintiffs, of the increased risk of birth defects associated with Zofran and aggressively promoted the product off-label to doctors, to hospitals, and directly to consumers.

38. 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.

39. 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.

40. As a direct and proximate result of the defective nature of Zofran, Jacob Cox was caused to suffer serious birth defects that are permanent and lasting in nature, disfigurement, physical pain and mental anguish, including diminished enjoyment of life, embarrassment, loss of self-esteem, as well as the need for lifelong medical and dental treatment, monitoring and/or medications.

COUNT IV
FRAUDULENT MISREPRESENTATION

41. As a cause of action and ground for relief, plaintiff alleges the

factual matters described in paragraphs No. 1 through 40, inclusive, of the complaint as a part of this count.

42. GSK falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff Jill Cox and her providers, that:

(a) Zofran was safe and effective for treating pregnancy related nausea;

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

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

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

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

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

45. 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 Jill Cox 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 Plaintiffs herein.

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

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

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

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

COUNT V
FRAUDULENT CONCEALMENT

50. As a cause of action and ground for relief, plaintiff alleges the factual matters described in paragraphs No. 1 through 49, inclusive, of the complaint as a part of this count.

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

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

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

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

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

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

(f) Zofran is not safe and effective for treating pregnancy related nausea; and

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

52. 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 Jill Cox inducing them into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

53. GSK knew that physicians, hospitals, healthcare providers and

expectant mothers such as Plaintiff Jill Cox had no way to determine the truth behind GSK's concealment and material omissions of facts surrounding Zofran, as set forth herein.

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

COUNT VI
NEGLIGENT MISREPRESENTATION

55. As a cause of action and ground for relief, plaintiff alleges the factual matters described in paragraphs No. 1 through 54, inclusive, of the complaint as a part of this count.

56. GSK falsely and negligently represented to the medical community and expectant mothers, including Plaintiffs and their providers, that:

(a) Zofran was safe and effective for treating pregnancy related nausea;

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

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

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

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

COUNT VII
BREACH OF EXPRESS WARRANTY

58. As a cause of action and ground for relief, plaintiff alleges the factual matters described in paragraphs No. 1 through 57, inclusive, of the complaint as a part of this count.

59. Defendant expressly warranted that:

(a) Zofran was safe and effective for treating pregnancy related nausea;

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

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

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

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

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

62. 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.

63. 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.

COUNT VIII
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE

64. As a cause of action and ground for relief, plaintiff alleges the factual matters described in paragraphs No. 1 through 63, inclusive, of the complaint as a part of this count.

65. GSK is a merchant with respect to goods of the kind Plaintiffs received. GSK impliedly warranted that its product was merchantable. GSK impliedly warranted that its product was fit for the particular purpose of being used safely in the treatment of pregnancy-related nausea. Plaintiffs and their

health care providers relied on GSK's skill and judgment when deciding to use GSK's product.

66. 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 Plaintiffs and their medical providers.

67. 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.

68. Plaintiffs serve reasonable notice of the breach by defendant, who did not cure the breach.

COUNT IX
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

69. As a cause of action and ground for relief, plaintiff alleges the factual matters described in paragraphs No. 1 through 68, inclusive, of the complaint as a part of this count.

70. Plaintiffs Cory and Jill Cox were shocked when Jacob Cox was

born with a birth defect. They made inquiry of their medical providers to make sure that their child was not unnecessarily exposed to any substance that could cause birth defects and were told she was not.

71. Three months after the birth of Jacob Cox, Plaintiffs Cory and Jill Cox watched their son undergo corrective surgery, resulting in a permanent scar. Plaintiffs continue to provide essential care and comfort for Jacob Cox, including many tests and procedures related to the cleft palate.

72. Plaintiffs Cory and Jill Cox cared for and provided support to Jacob Cox as he experienced developmental delays, learning to walk and talk more slowly than the average infant.

73. At all times mentioned herein, it was foreseeable to Defendant that its intentional or negligent actions and omissions would cause serious or severe emotional distress to Plaintiffs Cory and Jill Cox.

74. As a direct and proximate result of Defendant's conduct, Plaintiffs Cory and Jill Cox have suffered severe emotional distress including horror, grief, shame, humiliation, anger, disappointment, worry, reflux, sleeplessness, and anxiety in learning that Jacob Cox was born with a birth defect, dealing with the years of care, medical procedures and attendant worry, and then discovering years later that Jacob Cox was unnecessarily exposed to Zofran, a drug that caused him birth defect of cleft palate, and may cause other life

threatening birth defects like heart defects. The fear and shock of such a discovery of the cause and the culpable party after the lengthy medical ordeal and history of care is of a nature that no reasonable parent could or should be forced to endure.

DAMAGES

75. Plaintiffs sustained injuries and damages, as a result of this incident, which injuries and damages consist of, but are not limited to, the following, viz:

(a) General damages in a sum in excess of the jurisdictional minimum of this Court;

(b) Pain and suffering experienced by Plaintiffs as a result of Jacob Cox's birth defects;

(c) Medical, incidental, and hospital expenses according to proof;

(d) Other special damages including the financial losses incurred by the Cox family in caring for Jacob Cox;

(e) A refund of all of the purchase costs of Zofran;

(f) Punitive damages in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;

(g) Pre-judgment and post-judgment interest as provided by law;

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

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

JURY DEMAND

76. Plaintiffs, pursuant to the Federal Rules of Civil Procedure, demand a jury trial on all factual issues.

CORY COX AND JILL COX, EACH INDIVIDUALLY and ON BEHALF OF JACOB COX, THEIR MINOR CHILD, Plaintiffs

By: _____

DAVID A. HODGES
Attorney at Law
Centre Place
212 Center Street, Fifth Floor
Little Rock, Arkansas 72201-2429
Arkansas Bar No. 65021
Telephone: (501) 374-2400
Facsimile: (501) 374-8926
E-Mail: david@hodgeslaw.com
Website: www.hodgeslaw.com