Exhibit 1

1522-CC10190 - SIMMONS ET AL V. GLAXOSMITHKLINE (E-CASE)

Case Header | Parties & Attorneys | Docket Entries | Charges, Judgments & Sentences | Service Information | Filings Due | Scheduled Hearings & Trials | Civil Judgments | Garnishments/ Execution

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08/19/2015 **Corporation Served**
Document ID - 15-SMCC-16920; Served To - GLAXOSMITHKLINE LLC; Server - ; Served Date - 11-AUG-15; Served Time - 11:00:00; Service Type - Sheriff Department; Reason Description - Served

08/07/2015 **Jury Trial Scheduled**
Scheduled For: 06/20/2016; 9:00 AM ; BRYAN L HETTENBACH; City of St. Louis

08/06/2015 **Judge/Clerk - Note**
Copy of Petition prepared for D Richardson.

08/05/2015 **Judge/Clerk - Note**
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08/03/2015 **Summons Issued-Circuit**
Document ID: 15-SMCC-16920, for GLAXOSMITHKLINE LLC.

Summ Req-Circ Pers Serv O/S
Request for Summons to Defendant GlaxoSmithKline, LLC; Electronic Filing Certificate of Service.
Filed By: ANDREW WILLIAM CALLAHAN
On Behalf Of: KIERRA SIMMONS, TIA HANCOCK, JOANNA TYLER, DAWN BARCHIESI

Note to Clerk eFiling
Filed By: ANDREW WILLIAM CALLAHAN

Notice
Memorandum of Payment; Electronic Filing Certificate of Service.
Filed By: ANDREW WILLIAM CALLAHAN
On Behalf Of: KIERRA SIMMONS, TIA HANCOCK, JOANNA TYLER, DAWN BARCHIESI

07/23/2015 **Entry of Appearance Filed**
Notice of Appearance; Electronic Filing Certificate of Service.
Filed By: JACOB ALEX FLINT
On Behalf Of: KIERRA SIMMONS

Judge/Clerk - Note
INSUFFICIENT FILING FEES OF 20.00 DOLLARS PLEASE MAKE THE FILING FEE MEMORANDUM TO THE ATTENTION OF CIVIL CASE INITIATION DEPARTMENT

07/22/2015 **Filing Info Sheet eFiling**
Filed By: JACOB ALEX FLINT

Pet Filed in Circuit Ct
Simmons et al v. GlaxoSmithKline LLC.
Filed By: JACOB ALEX FLINT
On Behalf Of: KIERRA SIMMONS

Judge Assigned

IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

KIERRA SIMMONS, Individually and as Parent and Natural Guardian of T.A., a Minor, TIA HANCOCK, Individually and as Parent and Natural Guardian of D.H., a Minor, JOANNA TYLER, Individually and as Parent and Natural Guardian of S.T., a Minor, and DAWN BARCHIESI, Individually and as Parent and Natural Guardian of M.B., a Minor Plaintiffs, v. GLAXOSMITHKLINE LLC, Defendant.	Cause No. **JURY TRIAL DEMANDED**

PETITION

COME NOW Plaintiffs, by and through their undersigned counsel, and for their cause of action against Defendant GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "Defendant") arising from Defendant's design, research, formulation, development, manufacture, sale, testing, marketing, advertising, promotion and/or distribution of the unsafe prescription medication Zofran, state as follows:

INTRODUCTION

1. Plaintiffs bring this cause of action against Defendant pursuant to Rule 52.05(a) of the Missouri Rules of Civil Procedure, as their claims arise out of the same series of transactions and occurrences, and involve common questions of law and fact. All claims in this action relate to wrongful conduct by Defendant in the research, design,

testing, formulating, inspecting, labeling, manufacturing, packaging, marketing, distributing, producing, processing, promoting and selling of the pharmaceutical drug known as Zofran, as set forth in further detail below. All Plaintiffs in this action seek recovery for damages sustained in the form of personal injuries that were directly and proximately caused by such wrongful conduct by Defendant, the unreasonably dangerous and defective nature of Zofran, and the attendant effects of Plaintiffs' personal injuries. Each of the personal injuries at issue in this action, and all of the claims in this action involve common legal and medical issues.

PARTIES

2. Plaintiff Kierra Simmons is a citizen of the City of St. Louis, State of Missouri. At all pertinent times, Plaintiff Kierra Simmons took brand name Zofran in the City of St. Louis, pursuant to a doctor's prescription and received brand name Zofran injections while hospitalized during her pregnancy with Minor Plaintiff, T.A.

3. On or around October 3, 2010, Plaintiff Kierra Simmons gave birth to Minor Plaintiff, T.A., who suffered a congenital heart malformation and the effects attendant thereto, as a direct and proximate result of the unreasonably dangerous and defective nature of Zofran and Defendant's wrongful and negligent conduct in the research, development, testing, manufacture, production, promotion, distribution, marketing, and sale of Zofran. As a direct and proximate result of these injuries, Plaintiff Kierra Simmons and her son T.A. have incurred and will incur medical expenses in the future, have endured and will endure pain and suffering and loss of enjoyment of life, and have otherwise been damaged in a personal and pecuniary nature.

4. Plaintiff Tia Hancock is a citizen of the City of Wilmington, State of Delaware. At all pertinent times, Plaintiff Tia Hancock took brand name Zofran in Delaware, pursuant to a doctor's prescription while pregnant with Minor Plaintiff, D.H.

5. On or around January 12, 2007, Plaintiff Tia Hancock gave birth to Minor Plaintiff, D.H., who suffered a congenital heart malformation and the effects attendant thereto, as a direct and proximate result of the unreasonably dangerous and defective nature of Zofran and Defendant's wrongful and negligent conduct in the research, development, testing, manufacture, production, promotion, distribution, marketing, and sale of Zofran. As a direct and proximate result of these injuries, Plaintiff Tia Hancock and her son D.H. have incurred and will incur medical expenses in the future, have endured and will endure pain and suffering and loss of enjoyment of life, and have otherwise been damaged in a personal and pecuniary nature.

6. Plaintiff Joanna Tyler is a citizen of the City of High Point, State of North Carolina. At all pertinent times, Plaintiff Joanna Tyler took brand name Zofran in North Carolina, pursuant to a doctor's prescription while pregnant with Minor Plaintiff, S.T.

7. On or around September 12, 2006, Plaintiff Joanna Tyler gave birth to Minor Plaintiff S.T., who suffered a congenital heart malformation and the effects attendant thereto, as a direct and proximate result of the unreasonably dangerous and defective nature of Zofran and Defendant's wrongful and negligent conduct in the research, development, testing, manufacture, production, promotion, distribution, marketing, and sale of Zofran. As a direct and proximate result of these injuries, Plaintiff Joanna Tyler and her daughter, S.T., have incurred and will incur medical expenses in the future, have endured and will endure pain and suffering and loss of enjoyment of life, and have otherwise been damaged in a personal and pecuniary nature.

8. Plaintiff Dawn Barchiesi is a citizen of the City of Waynesburg, State of Pennsylvania. At all pertinent times, Plaintiff Dawn Barchiesi took brand name Zofran in Pennsylvania, pursuant to a doctor's prescription while pregnant with Minor Plaintiff, M.B.

9. On or around August 23, 2004, Plaintiff Dawn Barchiesi gave birth to Minor Plaintiff M.B., who suffered a congenital heart malformation and the effects attendant thereto, as a direct and proximate result of the unreasonably dangerous and defective nature of Zofran and Defendant's wrongful and negligent conduct in the research, development, testing, manufacture, production, promotion, distribution, marketing, and sale of Zofran. As a direct and proximate result of these injuries, Plaintiff Dawn Barchiesi and her daughter, M.B., have incurred and will incur medical expenses in the future, have endured and will endure pain and suffering and loss of enjoyment of life, and have otherwise been damaged in a personal and pecuniary nature.

10. 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. GSK has identified its principal place of business in Wilmington, Delaware and has identified its headquarters in Pennsylvania and North Carolina.

11. GSK is the successor in interest to Glaxo, Inc. and Glaxo Wellcome Inc. Glaxo, Inc. was the sponsor of the original New Drug Application ("NDA") for Zofran. Glaxo, Inc., through its division Cerenex Pharmaceuticals, authored the original package insert and labeling for Zofran, including warnings and precautions attendant to its use. Glaxo Wellcome Inc. sponsored additional NDAs for Zofran, monitored and evaluated post-market adverse event reports arising from Zofran, and authored product labeling for Zofran. The term GSK used herein refers to GSK, its predecessors Glaxo, Inc. and Glaxo Wellcome Inc., and other GSK predecessors and/or affiliates that discovery reveals were involved in the testing, development, manufacture, marketing, sale and/or distribution of Zofran.

12. At all relevant times, Defendant GSK engaged in the business of research, designing, testing, formulating, inspecting, labeling, manufacturing, packaging,

marketing, distributing, producing, processing, promoting and selling the drug Zofran in the City of St. Louis and throughout Missouri and the United States.

JURISDICTIONAL ALLEGATIONS

13. Plaintiffs herein are properly joined pursuant to Rule 52.05(a) of the Missouri Rules of Civil Procedure. As detailed in this Petition, the claims of each of the Plaintiffs are logically related to each other. Each Minor Plaintiff herein was injured by being exposed to the Defendant's Zofran, as prescribed by a physician and/or a licensed healthcare provider to the Mother Plaintiff during her pregnancy with her Minor Plaintiff baby. In addition, other common facts include Minor Plaintiffs' injuries; each of the Minor Plaintiffs suffered an injury in the form of a congenital heart malformation and the attendant effects thereof as a direct and proximate result of being exposed to Zofran. All Plaintiffs' claims arise out of the same series of transactions by Defendant, who manufactured, researched, designed, tested, formulated, inspected, labeled, packaged, marketed, distributed, produced, processed, promoted, and sold the Zofran ingested by the Plaintiffs. Plaintiffs' claims, therefore, involve common questions of fact and law because Defendant's liability with regard to each Plaintiff is subject to the same legal requirements, as the Defendant's interactions with the scientific and medical community.

14. At all pertinent times, Defendant has conducted and continues to conduct continuous and systematic business in the State of Missouri sufficient to be at home in the State of Missouri, and sufficient to anticipate being sued in the State of Missouri. Defendant has also transacted business in the State of Missouri, including business giving rise to this action, maintained registered agents in the State of Missouri, and has committed torts in whole or in part in the State of Missouri, including torts giving rise to this action. Further, there is no federal subject matter jurisdiction because no federal question is raised

and some of the Plaintiffs and the Defendant are citizens of the same state, i.e., Delaware and/or Pennsylvania and North Carolina.

15. Venue is proper in this Court pursuant to Mo. Rev. Stat. 508.010 because the minor child of Plaintiff Kierra Simmons was first injured by Zofran in the City of St. Louis. At all pertinent times, Kierra Simmons used Zofran in the City of St. Louis, and the Minor Plaintiff was first injured while in the City of St. Louis, as the exposure to Zofran occurred in the City of St. Louis.

TIMELINESS AND TOLLING OF STATUTES OF LIMITATIONS

16. Plaintiffs filed this lawsuit within the applicable limitations period of first suspecting that Zofran was the cause of the Minor Plaintiffs' injuries. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the Minor Plaintiffs' Zofran-induced injuries at an earlier time, because, at the time of these injuries, the cause was unknown to Plaintiffs. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, the cause of these injuries, or the tortious nature of the conduct causing these injuries, until less than the applicable limitations period prior to the filing of this action.

17. Furthermore, the running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Through their affirmative misrepresentations and omissions—including but not limited to the off-label marketing of Zofran—Defendant actively concealed from Plaintiffs, and their prescribing physicians, the true risks associated with Zofran.

18. As a result of Defendant's actions, the Plaintiffs and their prescribing physicians were unaware, and could not reasonably know or learn through reasonable diligence that the Minor Plaintiffs had been exposed to the risks alleged herein, and that those risks were the direct and proximate result of Defendant's acts and omissions.

19. Through their affirmative misrepresentations and omissions pertaining to the safety of Zofran, Plaintiffs were prevented from discovering this information sooner because the Defendant herein misrepresented and continued to misrepresent to the public and to the medical community that Zofran was safe to take during pregnancy, and the Defendant has fraudulently concealed facts and information that could have led Plaintiffs to discover a potential cause of action.

20. Additionally, the Court should consider the economics of this fraud. The Defendant had the ability to and did spend enormous amounts of money in furtherance of their purpose and marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks.

21. The Plaintiffs and their prescribing physicians could not have afforded and could not have possibly conducted studies to determine the nature, extent, and identity of a related health risk, and were forced to rely on the Defendant's misrepresentations.

FACTUAL BACKGROUND

22. Zofran is a powerful drug developed by GSK to treat only those patients who were afflicted with the most severe nausea imaginable—that suffered as a result of chemotherapy or radiation treatments in cancer patients.

23. The U.S. Food and Drug Administration ("FDA") approved Zofran in 1991 for use in cancer patients who required chemotherapy or radiation therapy.

24. Although the only FDA approval for this drug was for seriously ill 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—otherwise known as "morning sickness." GSK did this despite having knowledge that such representations were utterly false, as GSK had never once undertaken a single study on the effects of this powerful drug on a pregnant mother or her growing child *in utero*.

Unlike another anti-nausea prescription drug available on the market—which is FDA-approved in the United States for treating morning sickness in pregnant women—GSK never conducted a single clinical trial before marketing Zofran to pregnant women. GSK simply chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment during pregnancy. GSK avoided conducting these studies because they would have hampered its marketing of Zofran and decreased profits by linking the drug to serious birth defects. GSK's conduct was tantamount to using expectant mothers and their unborn children as human guinea pigs.

25. As a result of GSK's fraudulent marketing campaign, Zofran was placed into the hands of unsuspecting pregnant women throughout the United States. These women ingested the drug because they naively believed that Zofran was an appropriate drug for use in their circumstance. When they ingested the drug, these pregnant women had no way of knowing that Zofran had never been studied in pregnant women, much less shown to be a safe and effective treatment for pregnancy-related nausea.

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

27. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date. GSK never disclosed these reports to

pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological studies that have demonstrated an elevated risk of developing birth defects such as those suffered in this case. GSK has not disclosed this to pregnant women or their physicians. Instead, GSK sales representatives specifically marketed and promoted Zofran as a morning sickness drug throughout the relevant time periods discussed herein.

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

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

30. GSK's written agreement with the United States reports GSK's settlement of claims that GSK:

> **(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 and pregnancy-related nausea)"**
>
> **(b) "made and/or disseminated unsubstantiated and false representations about the safety and efficacy of Zofran concerning the uses described in subsection (a) [hyperemesis and pregnancy-related nausea]"**
>
> **(c) "offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran**"

(Settlement Agreement, p. 5, July 2, 2012.)

31. GSK's conduct has caused devastating, irreversible, and life-long consequences and suffering to innocent newborns and their families, like Plaintiffs herein.

Mother Plaintiff Kierra Simmons

32. Plaintiff's minor child, T.A., was born in 2010 with a congenital

heart malformation after his mother, Plaintiff Kierra Simmons, was prescribed and began taking Zofran, and received Zofran injections, beginning early in her first trimester of pregnancy to alleviate the symptoms of morning sickness.

33. 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 never had been injured as described herein.

34. 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.

Mother Plaintiff Tia Hancock

35. Plaintiff's minor child, D.H., was born in 2007 with a congenital heart malformation after his mother, Plaintiff Tia Hancock, was prescribed Zofran in her first trimester of pregnancy to alleviate the symptoms of morning sickness.

36. 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 never had been injured as described herein.

37. 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.

Mother Plaintiff Joanna Tyler

38. Plaintiff's minor child, S.T., was born in 2006 with a congenital

heart malformation after her mother, Plaintiff Tia Hancock, was prescribed Zofran in her first trimester of pregnancy to alleviate the symptoms of morning sickness.

39. 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 never had been injured as described herein.

40. 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.

Mother Plaintiff Dawn Barchiesi

41. Plaintiff's minor child, M.B., was born in 2004 with a congenital heart malformation after her mother, Plaintiff Dawn Barchiesi, was prescribed Zofran in her first trimester of pregnancy to alleviate the symptoms of morning sickness.

42. 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 never had been injured as described herein.

43. 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.

Zofran Background

44. Zofran is a prescription drug indicated for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and

vomiting and post-operative nausea and/or vomiting:

> **INDICATIONS AND USAGE**
> 1. Prevention of nausea and vomiting associated with highly emetogenic **cancer chemotherapy**, including cisplatin ≥ 50 mg/m2.
> 2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic **cancer chemotherapy**.
> 3. Prevention of nausea and vomiting associated with **radiotherapy** in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
> 4. Prevention of **postoperative nausea and/or vomiting**.

(GSK, Zofran Prescribing Information, Sept. 2014)(emphasis added.)

45. The medical term for nausea and vomiting is emesis, and drugs that prevent or treat nausea and vomiting are called anti-emetics.

46. Zofran is part of a class of anti-emetics called selective serotonin 5HT3 receptor antagonists. The active ingredient in Zofran is ondansetron hydrochloride, which is a potent and selective antagonist at the 5-hydroxytryptamine receptor type 3 (5-HT3).

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

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

49. Zofran is available as an injection (2 mg/mL), a premixed injection (32 mg/50ml and 4 mg/50 ml), oral tablets (4 mg, 8 mg and 24 mg), orally disintegrating

tablets (4 mg and 8 mg) and an oral solution (4 mg/5 mL).

50. More specifically, GSK has obtained FDA approval for the following formations of Zofran:

a. NDA 20-007 – Zofran Injection (FDA approved January 4, 1991)

b. NDA 20-103 – Zofran Tablets (FDA approved December 31, 1992)

c. NDA 20-403 – Zofran Premixed Injection (FDA approved January 31, 1995)

d. NDA 20-605 – Zofran Oral Solution (FDA approved January 24, 1997)

e. NDA 20-781 – Zofran (a/k/a Zofran-Zydis) Orally Disintegrating Tablets (FDA approved January 27, 1999)

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

52. For GSK to market Zofran lawfully for the treatment of morning sickness in pregnant women, it must first adequately test the drug (including performing appropriate clinical studies) and formally submit to the FDA evidence demonstrating that the drug is safe and effective for treatment of morning sickness.

53. A team of the FDA's physicians, statisticians, chemists, pharmacologists, microbiologists and other scientists would then have an opportunity to: (a) review the company's data and evidence supporting its request for approval to market the drug; and (b) determine whether to approve the company's request to market the drug in the manner requested. Without first obtaining approval to market a drug for the treatment of pregnant women, a pharmaceutical company may not legally market its drug for that purpose.

54. GSK has not performed any clinical studies of Zofran use in pregnant women. GSK, however, had the resources and know-how to perform such studies, and such studies were performed to support another prescription drug that, unlike Zofran, is FDA-approved for the treatment of morning sickness.

55. GSK also has not submitted to the FDA any data demonstrating the safety or efficacy of Zofran for treating morning sickness in pregnant women. Instead, GSK has illegally circumvented the FDA-approval process by marketing Zofran for the treatment of morning sickness in pregnant women without applying for the FDA's approval to market Zofran to treat that condition or any other condition in pregnant women. This practice is known as "off-label" promotion, and in this case it constitutes fraudulent marketing.

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

GSK Knew that Zofran Presents an Unreasonable Risk of Harm to Babies Exposed in Utero

Preclinical Studies

57. Since at least the 1980s, when GSK received the results of the preclinical studies that it submitted in support of Zofran's NDA 20-007, GSK has known of the risk that Zofran ingested during pregnancy in mammals crosses the placental barrier to expose the fetus to the drug. For example, at least as early as the mid-1980s, GSK performed placental-transfer studies of Zofran in rats and rabbits, and reported that the rat and rabbit fetuses were exposed prenatally to Zofran during pregnancy.

58. The placental transfer of Zofran during human pregnancy at concentrations high enough to cause congenital malformations has been independently confirmed and detected in every sample of fetal tissue taken in a published study involving 41 pregnant patients. The average fetal tissue concentration of Zofran's active ingredient was 41% of the corresponding concentration in the mother's plasma.

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

60. Study No. R10937 was a Segment II teratological study of pregnant rats exposed to Zofran injection solution. Four groups of 40 pregnant rats (160 total) were reportedly administered Zofran through intravenous (I.V.) administration at doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. Clinical signs of toxicity that were observed in the pregnant rats included "low posture, ataxia, subdued behavior and rearing, as well as nodding and bulging eyes." No observations were reported as teratogenic effect.

61. 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 was noted—namely, areas of the parietal (body cavity) were not fully ossified, and the hyoid (neck) failed to ossify completely.

62. Study No. R10590 Oral Segment II was a 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.

63. Study No. L10649 Oral Segment II was a 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."

64. Even if animal studies do not reveal evidence of harm to a prenatally exposed fetus, that result is not necessarily predictive of human response. For example, a drug formerly prescribed to alleviate morning sickness, thalidomide, is an infamous teratogenic in humans, but animal studies involving the drug failed to demonstrate such an increased risk of birth defects in animals. GSK conducted studies of thalidomide and its toxicity before GSK developed Zofran and before it marketed Zofran for the treatment of morning sickness in pregnant women. Moreover, since at least 1993, GSK has stated in its prescribing information for Zofran that "animal reproduction studies are not always predictive of human response." Therefore, GSK has been aware since at least when it began marketing and selling Zofran that GSK could not responsibly rely on its animal studies as a basis for promoting Zofran use in pregnant women. But that is what GSK did.

Early Reports to GSK of Zofran-related Birth Defects to GSK

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

66. By 2000, GSK had received at least 32 reports of birth defects arising from Zofran treatment in pregnant women. These reports included congenital heart disease, dysmorphism, intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomaly, congenital musculoskeletal anomalies, and orofacial anomalies, among others.

67. In many instances, GSK received multiple reports in the same month, the same week and even the same day. For example, on or about September 13, 2000, GSK received three separate reports involving Zofran use and adverse events. For two of those incidents, the impact on the baby was so severe that the baby died.

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

69. 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.

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

Epidemiology Studies Examining the Risk of Congenital Heart Defects in Babies Who Were Exposed to Zofran in Utero

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

72. 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)("Pasternak

Study"); (2) Andersen, et al., *Ondansetron Use in Early Pregnancy and the Risk of Congenital Malformations—A Register Based Nationwide Control Study*, presented as International Society of Pharmaco-epidemiology, Montreal, Canada (2013)("Andersen Study"); and (3) Danielsson, et al., *Ondansetron During Pregnancy and Congenital Malformations in the Infant* (Oct. 31, 2014)("Danielsson Study").

73. Each of these studies includes methodological characteristics tending to bias its results toward under-reporting the true risk of having a child with a birth defect. Notwithstanding these characteristics biasing the results toward the null hypothesis, all three studies show elevated risk ratios for cardiac malformations, including risk ratios greater than 2.0. In other words, the studies report that a mother exposed to Zofran had more than a doubled risk of having a baby with a congenital heart defect as compared to a mother who did not ingest Zofran during pregnancy.

74. The Pasternak Study included data from the Danish National Birth Registry and examined the use of Zofran during pregnancy and risk of adverse fetal outcomes. Adverse fetal outcomes were defined as: spontaneous abortion, stillbirth, any major birth defect, pre-term delivery, low birth weight, and small size for gestational age. There were 608,385 pregnancies between January 2004 and March 31, 2011 examined. The unexposed group was defined as women who did not fill a prescription for ondansetron during the exposure time window. The exposure time window was defined as the first 12 week gestational period. Notably, the median fetal age at first exposure to Zofran was ten weeks, meaning that half of the cases were first exposed to Zofran after organogenesis (organ formation). This characteristic of the study led to an under-reporting of the actual risk of prenatal Zofran exposure. The study's supplemental materials indicated that women taking Zofran during the first trimester, compared to women who did not take Zofran, were 22% more likely to have offspring with a

septal defect, 41% more likely to have offspring with a ventricular septal defect and greater than four-times more likely to have offspring with atrioventricular septal defect.

75. The Andersen Study was also based on data collected from the Danish Medical Birth Registry and the National Hospital Register, the same data examined in the Pasternak Study. The Andersen study examined the relationship between Zofran use during the first trimester and subgroups of congenital malformations. Data from all women giving birth in Denmark between 1997 and 2010 were included in the study. A total of 903,207 births were identified in the study period with 1,368 women filling prescriptions for Zofran during the first trimester. The Andersen Study therefore used a larger data set (13 years) compared to the Pasternak Study (seven years). Exposure to the drug was also defined as filling a prescription during the first trimester, and prescription data were obtained from the National Prescription Registry. The Andersen study reported that mothers who ingested Zofran during their first trimester of pregnancy were more likely to have a child with a congenital heart defect than mothers who did not, and had a two-to four-fold greater risk of having a baby with a septal cardiac defect.

76. The Danielsson Study investigated risks associated with Zofran use during pregnancy and risk of cardiac congenital malformations from data available through the Swedish Medical Birth Registry. The Swedish Medical Birth Registry was combined with the Swedish Register of Prescribed Drugs to identify 1,349 infants born to women who had taken Zofran in early pregnancy from 1998-2012. The total number of births in the study was 1,501,434 infants, and 43,658 had malformations classified as major (2.9%). Among the major malformations, 14,872 had cardiovascular defects (34%) and 10,491 had a cardiac septum defect (24%). The Danielsson study reported a statistically significant elevated risk for cardiovascular defects for mothers taking Zofran versus those who did not. The results reported that the mothers who took Zofran during early

pregnancy had a 62% increased risk of having a baby with a cardiovascular defect. Further, mothers who took Zofran during pregnancy had a greater than two-fold increased risk of having a baby with a septal cardiac defect, compared to mothers who did not take Zofran during pregnancy.

77. In summary, since at least 1992, GSK has had mounting evidence showing that Zofran presents an unreasonable risk of harm to babies who are exposed to the drug during pregnancy. GSK has been aware that Zofran readily crosses human placental barriers during pregnancy. GSK has also been aware that the animal studies of Zofran cannot reliably support an assertion that Zofran can be used safely or effectively in pregnant women. Since 1992, GSK has received hundreds of reports of major birth defects associated with prenatal Zofran exposure. GSK also has had actual and/or constructive knowledge of the epidemiological studies reporting that prenatal Zofran exposure can more than double the risk of developing congenital heart defects. As alleged below, GSK not only concealed this knowledge from healthcare providers and consumers in the United States, and failed to warn of the risk of birth defects, but GSK also illegally and fraudulently promoted Zofran to physicians and patients specifically for the treatment of morning sickness in pregnant women.

GSK's Failure to Warn of the Risk of Birth Defects Associated with Prenatal Exposure to Zofran

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

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

80. 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.*

81. Federal law also required GSK to revise Zofran's labeling "**to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.**" *Id.* § 201.57(e) (emphasis added).

82. GSK has received hundreds of reports of birth defects associated with the non-FDA-approved use of Zofran in pregnant women. GSK has failed, however, to disclose these severe adverse events to healthcare providers or expectant mothers, including Plaintiffs and their prescribing healthcare providers.

83. Under 21 C.F.R. § 314.70(c)(2)(i), pharmaceutical companies were (and are) free to add or strengthen—without prior approval from the FDA—a contraindication, warning, precaution, or adverse reaction.

84. GSK thus had the ability and obligation to add warnings, precautions and adverse reactions to the product labeling for Zofran without prior approval from the FDA. GSK failed to do so.

85. Under 21 C.F.R. § 201.128, "if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put."

86. As of 1998 at least, 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.

87. GSK had the ability and obligation to state prominently in the Indications and Usage section of its drug label that there is a lack of evidence that Zofran is safe for the treatment of morning sickness in pregnant women. GSK failed to do so, despite GSK's knowledge that (a) the safety of Zofran for use in human pregnancy has not been established, and (b) there have been hundreds of reports of birth defects associated with Zofran use during pregnancy, and (c) epidemiology studies report an increased risk of birth defects in babies exposed to Zofran during pregnancy.

88. From 1993 to the present, despite mounting evidence of the birth defect risk, GSK's prescribing information for Zofran has included the same statement concerning use of Zofran during pregnancy:

> "**Pregnancy: Teratogenic Effects**: Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at I.V. doses up to 4 mg/kg per day and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed."

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

90. In the United States and in the State of Missouri 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.

91. 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. 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).

92. GSK had the ability, and indeed was required, to update Zofran's label to reflect at best a Pregnancy Category D designation or alternatively a Category X designation for Zofran:

> **Pregnancy Category D. If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans**, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: "Pregnancy Category D. See "Warnings and Precautions" section. Under the "Warnings and Precautions" section, **the labeling must state: "[drug] can cause fetal harm when administered to a pregnant woman. . . . If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."**

21 C.F.R. § 201.57(f)(6)(i)(d)(emphasis added).

> **Pregnancy Category X. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both**, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: "Pregnancy Category X. See `Contraindications' section." Under "Contraindications," **the labeling must state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman. . . . (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.**"

Id. § 201.57(f)(6)(i)(e)(emphasis added).

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

GSK has never updated Zofran's labeling to disclose that Zofran can cause fetal harm when administered to a pregnant woman, and GSK has failed to warn of the potential hazards to a fetus arising from Zofran use during pregnancy.

94. The FDA recently promulgated a final rule declaring that, as of June 2015, it will require pharmaceutical manufacturers to remove the current A, B, C, D, or X pregnancy categorization designation from all drug product labeling and instead summarize the risks of using a drug during pregnancy, discuss the data supporting that summary, and describe relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. 79 Fed. Reg. 72064 (Dec. 4, 2014). In promulgating this rule, the FDA "determined that retaining the pregnancy categories is inconsistent with the need to accurately and consistently communicate differences in degrees of fetal risk."

95. In summary, beginning years before Plaintiffs were 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 promoting it for use in pregnant women. This rendered the warnings accompanying Zofran inadequate and defective.

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

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

97. However, 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 Missouri.

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

99. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) notified GSK that the FDA had become aware of GSK's promotional materials for Zofran that violated the Federal Food Drug and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance." (FDA Ltr. to Michele Hardy, Director, Advertising and Labeling Policy, GSK, Mar. 9, 1999.)

100. GSK's promotional labeling under consideration included promotional statements relating the effectiveness of Zofran, such as "Zofran Can," "24-hour control," and other promotional messages. But the promotional labeling failed to present any information regarding the risks associated with use of Zofran.

101. 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**."

102. 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 had 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.

103. GSK's promotion of Zofran for use in pregnancy eventually led to a federal governmental investigation. On July 2, 2012 the Department of Justice announced that GSK "agreed to plead guilty and pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs," which included Zofran among numerous others. *See* DOJ Press Release, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012).

104. Part of GSK's civil liability to the government included payments arising from the facts that: (a) GSK promoted Zofran and disseminated false representations about the safety and efficacy of Zofran concerning pregnancy-related nausea and hyperemesis gravidarum, a severe form of morning sickness; and (b) GSK paid and offered to pay illegal remuneration to health care professionals to induce them to promote and prescribe Zofran.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

105. Plaintiffs repeat, reiterate and reallege each and every allegation of this Petition contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

106. 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.

107. 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.

108. 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 to 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 to 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 Plaintiffs, their healthcare providers, FDA, and the medical community that neither the safety nor the efficacy of Zofran for treating pregnancy-related nausea had 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.

109. 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.

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

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

112. Had the Mother Plaintiffs not taken Zofran, their babies would not have suffered those injuries and damages as described herein with particularity.

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

114. Plaintiffs also have sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their children.

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

116. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was done with reckless indifference to Plaintiffs' and the public's safety and welfare, justifying an award of punitive damages.

SECOND CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

117. Plaintiffs repeat, reiterate and reallege each and every allegation of this Petition contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

118. 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.

119. 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.

120. 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.

121. 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.

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

123. The Mother Plaintiffs also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their children.

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

125. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was done with reckless indifference to Plaintiffs' and the public's safety and welfare, justifying an award of punitive damages.

THIRD CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

126. Plaintiffs repeat, reiterate and reallege each and every allegation of this Petition contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

127. GSK falsely and fraudulently represented to expectant mothers and the medical and healthcare community, 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.

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

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

130. 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 Plaintiffs and their 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.

131. At the time the aforesaid representations were made by GSK and, at the time Plaintiffs used Zofran, they were unaware of the falsity of said representations and reasonably believed them to be true.

132. In reliance upon said representations, Plaintiffs' prescribers were induced to prescribe Zofran to them, and Plaintiffs were induced to and did use Zofran to treat pregnancy-related nausea.

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

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

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

136. The Mother Plaintiffs also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their children.

137. As a result of the foregoing acts and omissions, Plaintiffs require and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that their children will in

the future be required to obtain further medical and/or hospital care, attention, and services.

138. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was done with reckless indifference to Plaintiffs' and the public's safety and welfare, justifying an award of punitive damages.

FOURTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

139. Plaintiffs repeat, reiterate and reallege each and every allegation of this Petition contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

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

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

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

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

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

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

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

141. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran for pregnancy-related nausea were made purposefully, willfully, wantonly, and/or recklessly, to mislead physicians, hospitals and

healthcare providers, and expectant mothers including the Mother Plaintiffs into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

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

143. The Mother 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.

144. As a result of the foregoing acts and omissions, the Minor Plaintiffs were caused to suffer serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

145. The Mother Plaintiffs also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their children.

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

147. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was done with reckless indifference to Plaintiffs' and the public's safety and welfare, justifying an award of punitive damages.

FIFTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

148. Plaintiffs repeat, reiterate and reallege each and every allegation of this Petition contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

149. 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.

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

151. As a result of the foregoing acts and omissions, the Minor Plaintiffs suffered serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

153. The Mother Plaintiffs also have sustained severe emotional distress and

suffering as a result GSK's wrongful conduct and the injuries to their children.

154. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was done with reckless indifference to Plaintiffs' and the public's safety and welfare, justifying an award of punitive damages.

SIXTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

155. Plaintiffs repeat, reiterate and reallege each and every allegation of this Petition contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

156. GSK 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.

157. 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.

158. The Mother Plaintiffs and their healthcare providers did rely on the express warranties of GSK herein.

159. 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.

160. 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.

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

162. The Mother Plaintiffs also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their children.

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

164. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was done with reckless indifference to Plaintiffs' and the public's safety and welfare, justifying an award of punitive damages.

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

165. Plaintiffs repeat, reiterate and reallege each and every allegation of this Petition contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

166. 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.

167. 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.

168. 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.

169. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was done with reckless indifference to Plaintiffs' and the public's safety and welfare, justifying an award of punitive damages.

EIGHTH CAUSE OF ACTION
(FRAUD)

170. Plaintiffs repeat, reiterate and reallege each and every allegation of this Petition contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

171. GSK blatantly and intentionally distributed false information to the expectant mothers and the medical and healthcare community, 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.

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

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

174. When GSK made these representations, it knew they were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

175. 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 Plaintiffs and their 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.

176. At the time the aforesaid representations were made by GSK and, at the time Plaintiffs used Zofran, they were unaware of the falsity of these representations and reasonably believed them to be true.

177. In reliance upon said representations, Plaintiffs' prescribers were induced to prescribe Zofran to them, and Plaintiffs were induced to and did use Zofran to treat pregnancy-related nausea.

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

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

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

181. The Mother Plaintiffs also have sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their children.

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

183. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct. GSK's conduct was done with reckless indifference to Plaintiffs' and the public's safety and welfare, justifying an award of punitive damages.

PRAYER FOR RELIEF

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

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other noneconomic damages in an amount to be determined at trial of this action;

2. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determine at trial of this action;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendant and deter future similar conduct;

4. Prejudgment interest;

5. Postjudgment interest;

6. Awarding Plaintiffs reasonable attorneys' fees;

7. Awarding Plaintiffs the costs of these proceedings; and

8. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.

FLINT LAW FIRM LLC

By: s/Jacob A. Flint

Jacob A. Flint, #60740
Andrew W. Callahan, #60714
Flint & Associates, LLC
112 Magnolia Dr.
Glen Carbon, IL 62034
Phone: 618-288-4777
Fax: 618-288-2864
jflint@flintfirm.com
acallahan@flintfirm.com

IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

KIERRA SIMMONS, Individually and as Parent and Natural Guardian of T.A., a Minor, TIA HANCOCK, Individually and as Parent and Natural Guardian of D.H., a Minor, JOANNA TYLER, Individually and as Parent and Natural Guardian of S.T., a Minor, and DAWN BARCHIESI, Individually and as Parent and Natural Guardian of M.B., a Minor Plaintiffs, v. GLAXOSMITHKLINE LLC, Defendant.	Cause No. 1522-CC10190

NOTICE OF APPEARANCE

COMES NOW Andrew W. Callahan of the FLINT LAW FIRM, LLC and hereby enters his appearance as counsel of record for the Plaintiffs, TIA HANCOCK, Individually as Parent and Natural Guardian of D.H., a Minor, Joanna Tyler, Individually and as Parent and Natural Guardian of S.T., a Minor, and Dawn Barchiesi, Individually and as Parent and Natural Guardian of M.B., a Minor, in the above-captioned case.

FLINT LAW FIRM LLC

By: /s/ Andrew W. Callahan

Andrew W. Callahan, #60714
Jacob A. Flint, #60740
Flint & Associates, LLC
112 Magnolia Dr.
Glen Carbon, IL 62034
Phone: 618-288-4777
Fax: 618-288-2864
jflint@flintfirm.com
acallahan@flintfirm.com

IN THE 22ND JUDICIAL CIRCUIT COURT OF CITY OF ST LOUIS, MISSOURI

Judge or Division: BRYAN L HETTENBACH	**Case Number: 1522-CC10190**
Plaintiff/Petitioner: KIERRA SIMMONS **vs.**	Plaintiff's/Petitioner's Attorney/Address JACOB ALEX FLINT FLINT & ASSOCIATES LLC 112 MAGNOLIA DR GLEN CARBON, IL 62034
Defendant/Respondent: GLAXOSMITHKLINE LLC	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101
Nature of Suit: CC Pers Injury-Prod Liab	

(Date File Stamp)

Summons in Civil Case

The State of Missouri to: GLAXOSMITHKLINE LLC
Alias:

CSC LAWYERS INCORPORATING SERVICE COMPANY
221 BOLIVAR STREET
JEFFERSON CITY, MO 65101

COLE COUNTY SHERIFF

COURT SEAL OF
CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, a copy of which is attached, and to serve a copy of your pleading upon the attorney for Plaintiff/Petitioner at the above address all within 30 days after receiving this summons, exclusive of the day of service. If you fail to file your pleading, judgment by default may be taken against you for the relief demanded in the petition.

August 3, 2015
Date

Thomas Kloeppinger
Circuit Clerk

Further Information:

Sheriff's or Server's Return

Note to serving officer: Summons should be returned to the court within thirty days after the date of issue.

I certify that I have served the above summons by: (check one)

☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.

☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____ a person of the Defendant's/Respondent's family over the age of 15 years.

☐ (for service on a corporation) delivering a copy of the summons and a copy of the petition to

_____ (name) _____ (title).

☐ other _____.

Served at _____ (address)

in _____ (County/City of St. Louis), MO, on _____ (date) at _____ (time).

_____ Printed Name of Sheriff or Server

_____ Signature of Sheriff or Server

Must be sworn before a notary public if not served by an authorized officer:

(Seal)

Subscribed and sworn to before me on _____ (date).

My commission expires: _____ Date

_____ Notary Public

Sheriff's Fees, if applicable

Summons $_____
Non Est $_____
Mileage $_____ (____miles @ $._____per mile)
Total $_____

A copy of the summons and a copy of the petition must be served on **each** Defendant/Respondent. For methods of service on all classes of suits, see Supreme Court Rule 54.

IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

KIERRA SIMMONS, Individually and as Parent and Natural Guardian of T.A., a Minor, *et al.*,	)	
Plaintiffs,	)	
v.	)	Cause No. 1522-CC10190
GLAXOSMITHKLINE LLC,	)	
Defendant.	)	

REQUEST FOR ISSUANCE OF SUMMONS

COME NOW Plaintiffs, through the undersigned counsel, and hereby requests that Summons be issued to Defendant GlaxoSmithKline, LLC, to be served by the Cole County Sheriff's Department, to the following registered agent and address:

GlaxoSmith Kline, LLC
Registered Agent: CSC-Lawyers Incorporating Service Company
221 Bolivar Street
Jefferson City, MO 6510

FLINT LAW FIRM, LLC

By: /s/ Andrew W. Callahan

Andrew W. Callahan, #60714
Jacob A. Flint, #60740
Flint & Associates, LLC
112 Magnolia Dr.
Glen Carbon, IL 62034
Phone: 618-288-4777
Fax: 618-288-2864
jflint@flintfirm.com
acallahan@flintfirm.com

IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

KIERRA SIMMONS, Individually and as Parent and Natural Guardian of T.A., a Minor, *et al.*,	)	
Plaintiffs,	)	
v.	)	Cause No. 1522-CC10190
GLAXOSMITHKLINE LLC,	)	
Defendant.	)	

MEMORANDUM OF PAYMENT

COMES NOW Andrew W. Callahan, counsel for Plaintiffs, and hereby notifies the clerk that Plaintiffs have submitted payment in the amount of $20.00 to the St. Louis City Circuit Clerk's Office, via the Missouri E-Case filing system.

FLINT LAW FIRM, LLC

By: /s/ Andrew W. Callahan

Andrew W. Callahan, #60714
Jacob A. Flint, #60740
Flint & Associates, LLC
112 Magnolia Dr.
Glen Carbon, IL 62034
Phone: 618-288-4777
Fax: 618-288-2864
jflint@flintfirm.com
acallahan@flintfirm.com

IN THE 22ND JUDICIAL CIRCUIT COURT OF CITY OF ST LOUIS, MISSOURI

Judge or Division: BRYAN L HETTENBACH	**Case Number: 1522-CC10190**
Plaintiff/Petitioner: KIERRA SIMMONS 22ND JUDICIAL CIRCUIT CIRCUIT CLERK'S OFFICE BY _____ DEPUTY **vs.**	Plaintiff's/Petitioner's Attorney/Address JACOB ALEX FLINT FLINT & ASSOCIATES LLC 112 MAGNOLIA DR GLEN CARBON, IL 62034
Defendant/Respondent: GLAXOSMITHKLINE LLC	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101
Nature of Suit: CC Pers Injury-Prod Liab	

RECEIVED
AUG 10 2015
COLE COUNTY
SHERIFF'S OFFICE
(Date File Stamp)

Summons in Civil Case

The State of Missouri to: GLAXOSMITHKLINE LLC
Alias:
CSC LAWYERS INCORPORATING
SERVICE COMPANY
221 BOLIVAR STREET
JEFFERSON CITY, MO 65101

COLE COUNTY SHERIFF

COURT SEAL OF
CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, a copy of which is attached, and to serve a copy of your pleading upon the attorney for Plaintiff/Petitioner at the above address all within 30 days after receiving this summons, exclusive of the day of service. If you fail to file your pleading, judgment by default may be taken against you for the relief demanded in the petition.

August 3, 2015
Date

Thomas Kloeppinger
Thomas Kloeppinger
Circuit Clerk

2015 AUG 19 PM 10:
22ND JUDICIAL CIRCUIT
CIRCUIT CLERK'S OFFICE

Further Information:

Sheriff's or Server's Return

Note to serving officer: Summons should be returned to the court within thirty days after the date of issue.

I certify that I have served the above summons by: (check one)

☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.

☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with _____, a person of the Defendant's/Respondent's family over the age of 15 years.

ENTERED
AUG 28 2015

☒ (for service on a corporation) delivering a copy of the summons and a copy of the petition to LAUREN SHOPLEY (name) DESIGNEE (title).

☐ other _____.

Served at 350 E. HIGH ST TF (address)

in COLE (County/City of St. Louis), MO, on 8-11-15 (date) at 1100AM (time).

GREG WHITE
Printed Name of Sheriff or Server

By: Douglas R Blake #21
Signature of Sheriff or Server

Must be sworn before a notary public if not served by an authorized officer:

(Seal)

Subscribed and sworn to before me on _____ (date).

My commission expires: _____
Date

_____
Notary Public

Sheriff's Fees, if applicable

Summons	$_____
Non Est	$_____
Mileage	$_____ (____miles @ $._____per mile)
Total	$_____

$30 $30

A copy of the summons and a copy of the petition must be served on **each** Defendant/Respondent. For methods of service on all classes of suits, see Supreme Court Rule 54.