UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA

Julie Williams and Randall Williams, individually and as Parents and Natural Guardians of M.C.W., a Minor,	)	
Plaintiffs,	)	Civil No.
v.	)	
GLAXOSMITHKLINE LLC	)	JURY TRIAL DEMANDED
Defendants.	)	

NOTICE OF REMOVAL

Defendant GlaxoSmithKline LLC ("GSK"), removes the state court action entitled *Julie Williams, et al. v. GlaxoSmithKline LLC,* No. 16A-02416-5, from the Superior Court of Gwinnett County, Georgia, to the United States District Court for the Northern District of Georgia, Atlanta Division, pursuant to 28 U.S.C. §§ 1332, 1441, and 1446.[1] In support of the removal, GSK respectfully states as follows:

1. This is a pharmaceutical product liability case. On or about March 14, 2016, Plaintiffs Julie Williams and Randall Williams commenced this action by serving a summons and complaint ("Complaint") on GSK. A true and correct copy

[1]By removing this action to this Court, GSK does not waive any defenses, objections, or motions available under state or federal law. GSK expressly reserves the right to move for dismissal of some or all of Plaintiffs' claims and/or seek dismissal based on lack of personal jurisdiction, improper venue, and/or the doctrine of *forum non conveniens.*

of the summons and Complaint are attached to this Notice of Removal as Exhibit A. Plaintiffs assert claims for injuries and damages allegedly experienced by M.C.W. as a result of her mother's use of Zofran®, an FDA-approved prescription medicine manufactured by GSK. Plaintiffs bring claims against GSK for negligence, negligence per se, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation. (Compl. ¶¶ 105-170).

2. As explained below, this Court has original subject matter jurisdiction over this civil action pursuant to 28 U.S.C. § 1332, and the action may be removed to this Court under 28 U.S.C. § 1441 because (i) there is complete diversity of citizenship between Plaintiffs and Defendant, and (ii) the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

DIVERSITY OF CITIZENSHIP

3. GSK is, and was at the commencement of this action, a citizen of the State of Delaware for purposes of diversity jurisdiction.

4. GSK is a limited liability company. The sole member of GSK is, and was at the commencement of this action, GlaxoSmithKline Holdings (Americas) Inc. ("GSK Holdings"). Because Delaware is both GSK Holdings' state of incorporation and the location of its principal place of business, GSK Holdings is solely a citizen of Delaware. Therefore, GSK also is solely a Delaware citizen.

5. For purposes of diversity jurisdiction, determining the citizenship of

GSK is a two-step process. First, under the Eleventh Circuit's ruling in *Rolling Greens MHP, L.P. v. Comcast SCH Holdings L.L.C.*, 374 F.3d 1020, 1022 (11th Cir. 2004), a limited liability company is a citizen of any state of which a member of the company is a citizen. Second, under the Supreme Court's ruling in *Hertz Corp. v. Friend*, 130 S. Ct. 1181, 1185-86 (2010), a corporation is a citizen of the state in which it is incorporated and the state in which it has its principal place of business, as determined by the "nerve center" test.

6. Based on this two-step analysis, GSK is solely a citizen of Delaware. First, under *Rolling Greens*, GSK's citizenship is defined solely by the citizenship of its only member, GSK Holdings. Second, under *Hertz*, GSK Holdings is solely a citizen of Delaware, because it was incorporated under the laws of Delaware and has its principal place of business in Delaware. The sole member of GSK is GSK Holdings. Because Delaware is both GSK Holdings' state of incorporation and the location of its nerve center, GSK Holdings is solely a citizen of Delaware. Therefore, GSK also is solely a Delaware citizen. *See Johnson v. SmithKline Beecham Corp.*, 724 F.3d 337, 356-57, 360 (3d Cir. 2013).

7. Plaintiffs are now, and were at the commencement of this action, citizens of the State of Georgia. (Compl. ¶¶ 20-22).

8. Accordingly, there exists complete diversity among the parties because Plaintiffs are citizens of Georgia and GSK is a citizen of Delaware.

AMOUNT IN CONTROVERSY

9. It is apparent from the face of the Complaint and the serious injuries alleged that the amount in controversy exceeds $75,000. In the Complaint, Plaintiffs assert claims for injuries and damages allegedly experienced by M.C.W. as a result of prenatal exposure to Zofran®. (Compl. ¶ 11). Specifically, Plaintiffs contend that the use of Zofran® by Plaintiff Julie Williams during her pregnancy with M.C.W. caused M.C.W. to experience birth defects, including cleft palate. *Id.* Additionally, Plaintiffs allege that M.C.W. has undergone various surgeries and medical procedures, including a cleft palate repair, multiple myringotomies, and a sleep study, and is expected to undergo additional orthognathic surgeries and medical procedures in the future. (Compl. ¶¶ 11, 99). They also allege M.C.W. "has a dysmorphic appearance of the mandible that will require further medical attention as she grows." (Compl. ¶¶ 11, 99). Plaintiffs further allege that they "have suffered and incurred harm including severe and permanent pain and suffering, mental anguish, medical expenses and other economic and noneconomic damages, and M.C.W. will require more constant and continuous medical monitoring and treatment than had she not been exposed to Zofran." (Compl. ¶ 103).

10. Although the Complaint does not demand a specific dollar amount in damages, the preponderance of the evidence demonstrates that the matter in

controversy exceeds $75,000, exclusive of interest and costs. *See* 28 U.S.C. § 1446(c)(2)(B) (requisite amount in controversy may be demonstrated by "preponderance of the evidence").

11. As the Supreme Court recently held, a removing defendant is not required to provide evidence to support the amount in controversy in its Notice of Removal. "[A]ll that is required is a 'short and plain statement of the grounds for removal,' including 'a plausible allegation that the amount in controversy exceeds the jurisdictional threshold." *Dart Cherokee Basin Operating Co., LLC v. Owens*, 135 S. Ct. 547, 553-54 (2014).

12. Further, in cases involving allegations of congenital defects or birth injuries, juries nationwide have awarded plaintiffs in excess of $75,000 in damages. *See, e.g., Tobin v. Astra Pharm., Inc.*, No. 88-0350-L(CS), 1 Exp. Wit. 22873 (W.D. Ky. Mar. 8, 1991) (awarding $4.5 million to compensate plaintiff for congestive heart failure and heart transplant allegedly caused by use of defendant's prescription medication during pregnancy); *White v. Behlke*, 24 Nat. J.V.R.A.7:C1, 1000 WL 177472 (Pa. Com. Pl. Nov. 17, 2008) (awarding $20.5 million in damages for birth defects caused by defendant doctor's malpractice); *Estrada v. Univ. of S. Fla. Bd. of Trustees*, 22 Nat. J.V.R.A. 10:C3, 2007 WL 7952305 (Fla. Cir. Ct. July 23, 2007) (awarding $23.55 million in damages as a result of a doctor's malpractice that resulted in plaintiff's child being born with birth defects),

collectively attached as Exhibit B. Indeed, numerous cases now pending against GSK in MDL No. 2657 located in the District of Massachusetts assert nearly identical claims as those alleged by Plaintiffs and seek damages in excess of $75,000.[2]

13. Based on the nature of the alleged injuries and claims, the requested relief, and jury verdicts and similar lawsuits from across the country, it is apparent from the face of the Complaint that Plaintiffs seek recovery in excess of $75,000, exclusive of interest and costs. The amount in controversy therefore exceeds the threshold for purposes of diversity jurisdiction under 28 U.S.C. § 1332(a).

14. Accordingly, this Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

[2] *See, e.g., Allen, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13756 (D. Mass.); *Bircher, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13857 (D. Mass.); *Coughlin, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13607 (D. Mass.); *M. Green, et al. v. GlaxoSmithKline LLC, et al.*, MDL No. 1:15-cv-13821 (D. Mass.); *Gruhn, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13709 (D. Mass.); *Julie Hunter, et al. v. GlaxoSmithKline PLC*, et al., MDL No. 1:15-cv-13569 (D. Mass.); *T. Hogan, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13729 (D. Mass.); *LeClair, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-10429 (D. Mass.); *Mandoyan, et al. v. GlaxoSmithKline LLC*, et al., MDL No. 1:15-cv-13564 (D. Mass.); *Marlenee, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13585 (D. Mass.); *Ragland, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13604 (D. Mass.); *Regan, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13612 (D. Mass.); *K. Roberts et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13710 (D. Mass.); *V. Roberts, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13584 (D. Mass.); *Trivisonno, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13708 (D. Mass.); and *Turnage, et al. v. GlaxoSmithKline LLC*, MDL No. 1:15-cv-13873 (D. Mass.).

OTHER PROVISIONS

15. This removal is timely. GSK files this Notice of Removal within 30 days of March 14, 2016, the date of service of the summons and Complaint upon GSK, as required by 28 U.S.C. § 1446(b).

16. The United States District Court for Northern District of Georgia, Atlanta Division, is the federal judicial district encompassing the Superior Court of Gwinnett County, Georgia, where this action is venued, such that this is the proper federal district for removal of this case to federal court. 28 U.S.C. § 1441(a); 28 U.S.C. § 90(a)(2).

17. A copy of all process, pleadings, and orders that have been served upon GSK is attached as Exhibit A to this Notice of Removal pursuant to 28 U.S.C. § 1446(a).

18. Pursuant to 28 U.S.C. § 1446(d), GSK will promptly file a copy of this Notice of Removal with the Superior Court of Gwinnett County, Georgia, and will serve a copy of same upon Plaintiffs.

19. By filing this Notice of Removal, GSK does not waive any jurisdictional or other defenses that might be available to it.

20. GSK reserves the right to amend or supplement this Notice of Removal.

WHEREFORE, Defendant GSK hereby removes this action from the

Superior Court of Gwinnett County, Georgia, to the United States District Court for the Northern District of Georgia, Atlanta Division, pursuant to 28 U.S.C. §§ 1332, 1441, and 1446, and states that no further proceedings may be had in the state action.

Dated: April 12, 2016

Respectfully submitted,

/s/ Leonard Searcy, II
Leonard Searcy, II
Georgia Bar No. 633303
SHOOK HARDY & BACON LLP
2555 Grand Blvd.
Kansas City, MO 64108
Telephone: (816) 474-6550
Fax: (816) 421-5547
E-mail: lsearcy@shb.com

ATTORNEYS FOR DEFENDANT GLAXOSMITHKLINE LLC

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Notice of Removal will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent via first class mail to those identified as non-registered participants.

/s/ Leonard Searcy, II

ATTORNEY FOR DEFENDANT GLAXOSMITHKLINE LLC

EXHIBIT A

CORPORATION SERVICE COMPANY®

Notice of Service of Process

null / ALL
Transmittal Number: 14904609
Date Processed: 03/14/2016

Primary Contact: Kathy Allen
GlaxoSmithKline LLC
5 Crescent Drive
Philadelphia, PA 19112-1001

Copy of transmittal only provided to: Gwen Sutton
Janice Landwehr
Legal Department
Debra Cranford

Entity:	GlaxoSmithKline LLC Entity ID Number 2850154
Entity Served:	GlaxoSmithKline LLC
Title of Action:	Julie Williams vs. Glaxosmithkline LLC
Document(s) Type:	Summons/Complaint
Nature of Action:	Product Liability
Court/Agency:	Gwinnett County Superior Court, Georgia
Case/Reference No:	16M 02416-5
Jurisdiction Served:	Georgia
Date Served on CSC:	03/14/2016
Answer or Appearance Due:	30 Days
Originally Served On:	CSC
How Served:	Personal Service
Sender Information:	Robert C. Buck 678-338-4999

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To avoid potential delay, please do not send your response to CSC

CSC is SAS70 Type II certified for its Litigation Management System.

IN THE SUPERIOR COURT OF GWINNETT COUNTY

STATE OF GEORGIA

Julie Williams and Randall Williams,
Individually and as Parents and Natural
Guardians of M.C.W., a Minor

PLAINTIFF

VS.

GlaxoSmithKline LLC

DEFENDANT

16A 02416-5

CIVIL ACTION
NUMBER:_____

GlaxoSmithKline LLC
through its registered agent,
Corporation Service Company,
40 Technology Parkway South
Suite 300, Gwinnett, Norcross, GA, 30092

SUMMONS

TO THE ABOVE NAMED DEFENDANT:

You are hereby summoned and required to file with the Clerk of said court and serve upon the Plaintiff's attorney, whose name and address is:

Buck Law Firm
1050 Crown Pointe Parkway
Suite 940, Atlanta, GA, 30338

an answer to the complaint which is herewith served upon you, within 30 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint.

This 10 **day of** March, **20**16.

Richard T. Alexander, Jr.,
Clerk of Superior Court

By Deanne Parker
Deputy Clerk

INSTRUCTIONS: Attach addendum sheet for additional parties if needed, make notation on this sheet if addendum sheet is used.

SC-1 Rev. 2011

IN THE SUPERIOR COURT OF GWINNETT COUNTY
STATE OF GEORGIA

Julie Williams and Randall Williams, individually and as Parents and Natural Guardians of M.C.W., a Minor, Plaintiffs, v. GlaxoSmithKline LLC Defendant.	Case No.: _____ COMPLAINT JURY DEMANDED 16A 02416-5

COMPLAINT FOR DAMAGES

COME NOW Plaintiffs, Julie Williams and Randall Williams, individually and on behalf of their daughter, M.C.W. ("Plaintiffs") who by and through the undersigned counsel hereby state their Complaint for Damages as follows:

INTRODUCTION

1. 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.

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

3. Although the only FDA approval for this drug was for seriously ill patients, GlaxoSmithKline LLC ("GSK") marketed Zofran "off label" since at least January 1998 as an established 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 further

marketed Zofran during this time as a "wonder drug" for pregnant women, despite having knowledge that GSK had never once undertaken a single study establishing that this powerful drug was safe or effective for pregnant mothers and their growing children *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 establishing the safety and efficacy of Zofran for treating pregnant women before GSK marketed Zofran for the treatment of pregnant women. GSK, in fact, excluded pregnant women from its clinical trials used to support its application for FDA approval of Zofran. In short, 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 and buried any internal analyses of Zofran's teratogenic potential 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.

4. As a result of GSK's nationwide fraudulent marketing campaign, Zofran was placed into the hands of unsuspecting pregnant women and in the 2000s became the number one most prescribed drug for treating morning sickness in the United States. These women ingested the drug because they innocently 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. Zofran *would never* have become the most prescribed morning sickness drug in the United States, and Plaintiff Julie Williams would never have taken it, if GSK had not misleadingly marketed the drug as a safe and efficacious treatment for morning sickness.

5. By contrast, GSK knew that Zofran was unsafe for ingestion by expectant mothers. In the 1980s, GSK conducted animal studies, which 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. GSK did not disclose this material information to pregnant women or their physicians.

6. 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, including reports of the same craniofacial anomalies suffered by Z.E. GSK never disclosed these reports to pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological and mechanistic studies that have demonstrated an elevated risk of developing Zofran-induced birth defects such as those suffered in this case. GSK has not disclosed this material information to pregnant women or their physicians. Instead, GSK sales representatives specifically marketed and promoted Zofran as a morning sickness drug since at least January 1998.

7. 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. In exchange for GSK's full performance of its criminal plea agreement with the United States and for certain other promises exchanged between GSK and the United States, the United States agreed not to prosecute GSK criminally for conduct relating to "GSK's sales, marketing and promotion of . . . Zofran between January 1998 and December 2004." (Agreement between United States and GSK, pp. 1-2, June 27, 2012.)

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

9. GSK's civil settlement 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.)

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

11. Plaintiffs' minor child, M.C.W. was born on [redacted], 2004 with congenital defects after her mother, Plaintiff Julie Williams, ingested Zofran beginning early in her first trimester of pregnancy to alleviate the symptoms of morning sickness. M.C.W. has had to undergo various surgeries and medical procedures including, but not limited to a cleft palate repair and myringotomy ([redacted]), a sleep study ([redacted]), a myringotomy ([redacted], a myringotomy ([redacted] and is expected to undergo future orthognathic surgeries and other related medical procedures in the future. M.C.W. has a dysmorphic appearance of the mandible that will require further medical attention as she grows.

12. M.C.W. was exposed to Zofran *in utero* during the periods when each of these tissues was forming and susceptible to developmental insult from environmental exposure.

13. There is no known genetic cause for M.C.W. 's condition. M.C.W. has no family history of any of the conditions from which she suffers.

14. Had Plaintiffs known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, Plaintiff Julie Williams would never have taken Zofran, and her child would never have been injured as described herein.

15. Plaintiffs bring claims for compensatory 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.

JURISDICTION AND VENUE

17. This Court has jurisdiction over this action because it relates to various torts occurring in the State of Georgia as incurred by citizens and residents of Georgia.

19. At all times herein mentioned, GSK conducted, and continues to conduct, a substantial amount of business activity and has committed a tort, in whole or in part, in this judicial district. GSK is registered to conduct business in this district, with its Resident Agent, Corporation Service Company located at 40 Technology Parkway South, Suite 300, Gwinnett, Norcross, Georgia, 30092, and engaged in interstate commerce when they advertised, promoted, supplied, and sold pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in this district. Although GSK's plan to misleadingly market Zofran for pregnancy was devised outside this district and State, it was executed nationwide, including in this district and State.

PARTIES

20. Plaintiff, Julie Williams, is a resident and citizen of the State of Georgia. She is the mother and natural guardian of M.C.W.

21. Plaintiff, Randall Williams, is a resident and citizen of the State of Georgia. He is the spouse of Julie Williams and the father and natural guardian of M.C.W.

22. Plaintiffs Julie Williams and Randall Williams live in Norcross, Gwinnett County, Georgia with M.C.W. their minor child.

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

24. Defendant 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. GSK continued to be the holder of the NDA for Zofran at all times material to this action.

25. At all relevant times, Defendant GSK conducted business in the State of Georgia and has derived substantial revenue from products, including Zofran, sold in Georgia.

PERTINENT BACKGROUND ON ZOFRAN

26. 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.)

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

28. 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).

29. 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.

30. 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).

31. 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).

32. 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)

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

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

GSK's Knowledge That Zofran Presents an Unreasonable Risk of Harm to Babies Who Are Exposed to It During Pregnancy

Preclinical Studies

39. 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.

40. 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.

41. 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).

42. 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 effects.

43. 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 off-spring and fetuses were noted – namely, areas of the parietal (body cavity) were not fully ossified, and the hyoid (neck) failed to ossify completely.

44. Study No. R10590 Oral Segment II teratological study of rats. Four groups of 30 pregnant rats (120 total) were given Zofran orally at doses of 0, 1, 4 and 15 mg/kg/day, respectively. Subdued behavior, labored breathing, which is a symptom of congenital heart defects, and dilated pupils were observed in the 15 mg/kg/day group. Body weight, gestational duration and fetal examinations were reported as normal, but "slight retardation in skeletal ossification" was noted in the offspring.

45. Study No. L10649 Oral Segment II teratological study of rabbits. Four groups of 14-18 pregnant rabbits (56-64 total) were given Zofran orally at doses of 0, 1, 5.5 and 30 mg/kg/day. The study reported lower maternal weight gain in all of the exposed groups, as well as premature delivery and "total litter loss," referring to fetal deaths during pregnancy in the 5.5 mg/kg/day group. Examination of the fetuses showed "slight developmental retardation as evident by incomplete ossification or asymmetry of skeleton."

46. 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

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

48. 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.

49. 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.

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

51. 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.

52. 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 During Pregnancy

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

54. Three recent epidemiological studies have examined the association between prenatal exposure to Zofran and the risk of congenital heart defects in babies. These studies include: (1) Pasternak, et al., *Ondansetron in Pregnancy and Risk of Adverse Fetal Outcomes*, New England Journal of Medicine (Feb. 28, 2013) (the "Pasternak Study"); (2) Andersen, et al., *Ondansetron Use in Early Pregnancy and the Risk of Congenital Malformations— A Register Based Nationwide Control Study*, presented as International Society of Pharmaco-epidemiology, Montreal, Canada (2013) (the "Andersen Study"); and (3) Danielsson, et al., *Ondansetron During Pregnancy and Congenital Malformations in the Infant* (Oct. 31, 2014) (the "Danielsson Study").

55. 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.

56. 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.

57. 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 than mothers who did not to have a child with a congenital heart defect, and had a two- to four-fold greater risk of having a baby with a septal cardiac defect.

58. 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 significantly 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.

59. 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 pregnancy women.

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

60. 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) (emphasis added).

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

62. 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.*

63. 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).

64. 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 Julie Williams and her prescribing healthcare provider.

65. 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.

66. By contrast, the U.S. Supreme Court has declared that a generic drug manufacturer cannot unilaterally add to or strengthen a contraindication, warning, precaution or adverse reaction.

Wyeth, Inc. v. Weeks, 159 So. 3d 649, 660 (Ala. 2014) (citing PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (U.S. 2011).

67. 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. Had GSK done so, the manufacturers of generic bioequivalent versions of Zofran would have been required to make the same additions. *Id.* at 660-661.

68. 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."

69. At least as of 1998, 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.

70. 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.

71. 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."

72. 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 not recommended**."

73. In the United States and in this State specifically, GSK has at all relevant times failed to include any warning disclosing any risks of birth defects arising from Zofran use during pregnancy in Zofran's prescribing information or other product labeling.

74. GSK's inclusion of the phrase "Pregnancy Category B" in Zofran's prescribing information refers 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).

75. 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).

76. Beginning at least in 1992, GSK had positive evidence of human fetal risk posed by Zofran based 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.

77. 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."

78. In summary, beginning years before Plaintiff Julie Williams was exposed to Zofran, GSK marketed and sold Zofran without adequate warning to healthcare providers and consumers that Zofran was causally associated with an increased risk of birth defects, and that GSK had not adequately tested Zofran to support marketing and promotion it for use in pregnant women. This rendered the warnings accompanying Zofran inadequate and defective.

79. Plaintiffs hereby demand that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiffs Julie Williams and similarly situated mothers and mothers-to-be, as GSK's wrongful conduct alleged herein is continuing. Plaintiffs further demand that GSK fully and fairly comply to remove the Pregnancy Category B designation from its drug product labeling for Zofran and fully and accurately summarize the risks of using Zofran during pregnancy, fully and accurately describe the data supporting that summary, and fully and accurately describe the relevant information to help health care providers make informed prescribing decisions and counsel women about the risks associated with use of Zofran during pregnancy.

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

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

81. But 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, which before its patent

expiration in 2006 was one of the most expensive drugs available in the United States market. 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 this State.

82. At least as early as January 1998, 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 including those in this State, among others, as a safe treatment alternative for morning sickness in pregnant women.

83. In support of its off-label marketing efforts, at least as early as January 1998, GSK offered and paid substantial remuneration to healthcare providers and "thought leaders" to induce them to promote and prescribe Zofran to treat morning sickness.

84. 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.)

85. 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.

86. 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.**"

87. GSK disregarded this mandate by the FDA. For example, as early as 2000, GSK's marketing materials in widely circulated obstetrician and gynecology trade journals over-emphasized Zofran's "Pregnancy Category B" designation as an imprimatur of safeness for use in pregnancy on the very first page of the marketing material and without adequate risk information. This created a false impression to busy healthcare practitioners that the safety of use in pregnancy has been established. GSK's materials failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran treatment during pregnancy.

88. When the FDA first approved Zofran to treat cancer patients, GSK's Oncology Division sales force had primary responsibility for marketing and promoting the drug. Beginning in at least January 1998, GSK set out to expand its Zofran sales to obstetricians and gynecologists by promoting Zofran as an established safe and effective treatment for morning sickness. GSK's initial strategy in this regard required its sales force to create new relationships with obstetricians and gynecologists by adding them as "new accounts." While this strategy had some success, it was inefficient compared to a revised promotional strategy that would enable GSK to leverage its other division's already established relationships with obstetricians and gynecologists. Thus, GSK's Oncology Division began partnering with GSK's Consumer Healthcare Division to promote Zofran.

89. Specifically, in or about 2001, GSK's Oncology Division finalized a co-marketing agreement with GSK's Consumer Healthcare Division under which sales representatives from GSK's Consumer Healthcare Division would market Zofran to obstetricians and gynecologists.

At the time GSK's Consumer Healthcare Division sales force already had established relationships with, and routinely called on, obstetricians and gynecologists to promote and provide samples of another GSK product, Tums®, specifically for the treatment and prevention of heartburn during pregnancy. GSK's established network for promoting Tums for use in pregnancy afforded it an efficient additional conduit for promoting Zofran for use in pregnancy.

90. GSK's primary purpose in undertaking this co-marketing arrangement was to promote Zofran to obstetricians and gynecologists during GSK's Consumer Healthcare Division sales force visits to obstetricians' and gynecologists' offices. Although some obstetricians and gynecologists performed surgeries and could order Zofran for post-operative nausea, the central focus of GSK's co-marketing effort was to promote Zofran for the much more common condition of morning sickness in pregnancy, and thus increase sales and profits.

91. GSK's Zofran sales representatives received incentive-based compensation that included an annual salary and a quarterly bonus. The bonus amount was determined by each sales representative's performance in the relevant market and whether she or he attained or exceeded quarterly sales quotas. The more Zofran sold by a GSK sales representative or prescribed by a provider in that representative's sales territory, the greater his or her compensation and other incentives would be.

92. As a result of GSK's fraudulent marketing campaign, the precise details of which are uniquely within the control of GSK, Zofran achieved blockbuster status by 2002 and became the number one most prescribed drug for treating morning sickness in the United States. In 2002, sales of Zofran in the United States totaled $1.1 billion, while global Zofran sales were approximately $1.4 billion in 2002.

93. 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).

94. 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.

95. GSK's 2012 civil settlement with the United States covered improper promotional conduct that was part of an overarching plan to maximize highly profitable Zofran sales without due regard to laws designed to protect patient health and safety. Another component of that plan led to a separate $150 million settlement between GSK and the United States in 2005. In or around 1993, a GSK marketing document sent to all of its sales and marketing personnel nationwide advised that they should emphasize to medical providers not only the benefits of Zofran but also the financial benefits to the providers by prescribing Zofran. Specifically, "[b]y using a 32 mg bag [of Zofran], the physician provides the most effective dose to the patient and increases his or her profit by $___ in reimbursement." GSK's marketing focus on profits to the prescribers misleadingly aimed to shift prescribers' focus from the best interests of patients to personal profit. In this regard, GSK marketed Zofran beginning in the 1990s as "convenient" and offering "better reimbursement" to prescribers.

GSK detailed this plan in a marketing document for its Zofran premixed IV bag entitled "Profit Maximization – It's in the Bag." Upon information and belief, GSK's conduct in this paragraph continued until the DOJ began investigating it in the early 2000s.

Plaintiffs' Exposures to Zofran

96. Plaintiff, Julie Williams, is the mother and natural guardian of M.C.W.

97. To alleviate and prevent the symptoms of morning sickness, Plaintiff Julie Williams was prescribed Zofran during her pregnancy in 2003.

98. M.C.W. was born on [redacted], 2004.

99. M.C.W. was born with cleft palate which has already required surgical repair and suffers from other physical impairments which have required her to undergo various medical procedures which include a myringotomy ([redacted], a sleep study [redacted], a myringotomy [redacted], a myringotomy ([redacted]. M.C.W. is expected to undergo future orthognathic surgeries and other related medical procedures in the future. M.C.W. has a dysmorphic appearance of the mandible that will require further medical attention as she grows. M.C.W. was exposed to Zofran *in utero* during the periods when each of these tissues was forming and susceptible to developmental insult from environmental exposure.

100. There is no known genetic cause for M.C.W. condition. M.C.W. has no family history of any of the conditions from which she suffers.

101. Plaintiff Julie Williams was unaware of the dangerousness of Zofran or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during pregnancy.

102. Had Plaintiff Julie Williams and her prescribers known of the increased risk of birth defects associated with Zofran/ondansetron, and had they not been misled by Defendant's promotion of the drug's purported safety benefits for use in pregnancy (on which they reasonably relied), Plaintiff would not have taken Zofran/ondansetron during pregnancy and M.C.W. would not have been born with congenital malformations.

103. As a direct and proximate result of Defendant's conduct, Plaintiffs and their daughter M.C.W. have suffered and incurred harm including severe and permanent pain and suffering, mental anguish, medical expenses and other economic and noneconomic damages, and will require more constant and continuous medical monitoring and more treatment than had they not been exposed to Zofran.

104. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that Defendant's wrongful conduct caused the appreciable harm sustained by their daughter, M.C.W. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful conduct that caused the injuries at an earlier time. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, the tortious nature of the conduct causing the injuries, until a short time before filing of this action. Additionally, Plaintiffs were prevented from discovering this information sooner because Defendant have misrepresented to the public and to the medical profession that Zofran/ondansetron is safe for use in pregnancy, and Defendant have fraudulently concealed facts and information that could have led Plaintiffs to discover a potential cause of action. In all events, the statute of limitations is tolled for claims arising from injuries to minors. As such, Plaintiffs file this action within all applicable limitations periods.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

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

106. Defendant 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. Defendant owed this duty to Plaintiff Julie Williams and similarly situated individuals.

107. Defendant 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 Defendant 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 medical treatment, monitoring and/or medications.

108. Defendant, their 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 and financial incentives 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 Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Zofran for pregnant women;

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

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

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

i. Representing that Zofran was safe and efficacious for treating morning sickness and hyperemesis gravidarum when Defendant were 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 and craniofacial malformations;

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

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

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

o. Failing to advise Plaintiff, her healthcare providers, 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;

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

q. Failing to correct its misrepresentations that the safety and efficacy of Zofran for treating morning sickness had been established.

109. Despite the fact that Defendant knew or should have known that Zofran significantly increased the risk of birth defects, Defendant continued and still continues to negligently and misleadingly market, manufacture, distribute and/or sell Zofran to consumers. including Plaintiff. In doing so, Defendant failed to discharge its duty to Plaintiff Julie Williams, her prescribing physicians, the medical community and other expecting mothers.

110. Defendant knew or should have known that consumers such as Plaintiff Julie Williams would foreseeably use Zofran and/or its generic bioequivalent and rely upon representations made by GSK as the holder of the NDA for Zofran.

111. Defendant knew or should have known that consumers such as Plaintiff Julie Williams would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care, as set forth above.

112. Defendant's negligence as set forth above was the proximate cause of Plaintiffs' injuries, harm and economic loss, which Plaintiff M.C.W. and her parents suffered and/or will continue to suffer.

113. Had Plaintiff Julie Williams not taken Zofran/ondansetron, her baby would not have suffered those injuries and damages as described herein with particularity. Had Defendant marketed Zofran in a truthful and non-misleading manner, Plaintiff Julie Williams would never have taken Zofran and/or its generic bioequivalent.

114. As a result of the foregoing acts and omissions, M.C.W. was caused to suffer serious birth defects that are severe and permanent in nature, physical pain and mental

anguish, including diminished enjoyment of life, as well as the need for present and future medical treatment, monitoring and/or medications.

115. Plaintiffs Julie and Randall Williams also sustained severe emotional distress and suffering as a result Defendant's wrongful conduct and the injuries to their child.

116. As a result of the foregoing acts and omissions, M.C.W. requires 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 child will in the future be required to obtain further medical and/or hospital care, attention, and services.

117. By reason of the foregoing, Plaintiffs have been damaged by Defendant's wrongful conduct. Defendant's conduct was willful, wanton, reckless so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

SECOND CAUSE OF ACTION
(NEGLIGENCE PER SE)

118. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

119. Defendant 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.

120. Defendant 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 Defendant 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.

121. Defendant, their 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.

122. The laws violated by Defendant were designed to protect Plaintiff Julie Williams and similarly situated persons against the risks and hazards that have actualized in this case. Therefore, Defendant's conduct constitutes negligence per se.

123. Despite the fact that Defendant knew or should have known that Zofran significantly increased the risk of birth defects, Defendant continued and continue to negligently and misleadingly market, manufacture, distribute and/or sell Zofran to consumers, including Plaintiff Julie Williams.

124. Defendant knew or should have known that consumers such as Plaintiff Julie Williams would foreseeably use the Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

125. Defendant knew or should have known that consumers such as Plaintiff M.C.W. would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care, as set forth above.

126. Defendant's negligence was the proximate cause of M.C.W. 's injuries, harm and economic loss, which M.C.W. suffered and will continue to suffer.

127. Had Plaintiff Julie Willams not taken Zofran, her baby would not have suffered those injuries and damages as described herein. Had Defendant marketed Zofran in a truthful and

non-misleading manner, Plaintiff Julie Williams would never have taken Zofran and/or ondansetron its generic bioequivalent.

128. As a direct and proximate result of the defective nature of Zofran, M.C.W. was caused to suffer serious birth defects that are severe and permanent in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for present and future medical treatment, monitoring and/or medications.

129. Plaintiffs Julie and Randall Williams also sustained severe emotional distress and suffering as a result Defendant's wrongful conduct and the injuries to their child.

130. As a direct and proximate result of the foregoing acts and omissions, M.C.W. requires 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 child will in the future be required to obtain further medical and/or hospital care, attention, and services.

131. By reason of the foregoing, Plaintiffs have been damaged by Defendant's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

THIRD CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

132. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

133. Defendant committed actual and constructive fraud. GSK committed actual fraud by misrepresenting material facts on which Plaintiff and her healthcare providers acted. GSK committed constructive fraud by acting contrary to legal or equitable duties, trust, or confidence

upon which Plaintiffs relied, and by failing to act, though it should have. GSK's conduct constitutes constructive fraud because GSK breached legal and equitable duties and violated its fiduciary relationships to patients and healthcare providers.

134. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiff and her providers.

135. In violations of existing standards and duties of care, GSK made misrepresentations by means including, but not limited to, advertisements, labeling, marketing, marketing persons, notices, product information and written and oral information provided to patients and medical providers.

136. In violations of existing standards and duties of care, GSK intentionally, knowingly, falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff Julie Williams and her healthcare 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.

137. The representations made by Defendant were material, false and misleading.

138. When Defendant made these representations, it knew they were false or it did not know these representations were true, but made them anyway.

139. Defendant made these representations with the intent of defrauding and deceiving the public in general, and the medical and healthcare community in particular, and with the intent of inducing the public in general, and the medical and healthcare community in particular,

including Plaintiff Julie Williams and her providers, to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy-related nausea, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff Julie Williams and her daughter, M.C.W.

140. At the time the aforesaid representations were made by Defendant and, at the time Plaintiff Julie Williams used Zofran and/or its generic bioequivalent, she was unaware of the falsity of said representations and reasonably believed them to be true.

141. In reliance upon said representations, Plaintiff Julie Williams' healthcare provider was induced to prescribe Zofran and/or its generic bioequivalent to her, and Plaintiff Julie Williams was induced to and did use Zofran and/or its generic bioequivalent to treat pregnancy-related nausea. Had GSK not made the foregoing express and implied false statements about the product, Plaintiff's physician would not have recommended or prescribed Zofran and Plaintiff would not have used the product.

142. Plaintiff Julie Williams, her prescribing physicians and the medical community justifiably relied on said representations.

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

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

145. Defendant knew or should have known that consumers such as Plaintiff would foreseeably use Zofran and/or its generic bioequivalent and rely upon representations made by GSK as the holder of the NDA for Zofran.

146. As a direct and proximate result of the defective nature of Zofran, M.C.W. was 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 present and future medical treatment, monitoring and/or medications.

147. Plaintiffs Julie and Randall Williams also sustained severe emotional distress and suffering as a result Defendant's wrongful conduct and the injuries to their child.

148. As a direct and proximate result of the foregoing acts and omissions, M.C.W. requires 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 child will in the future be required to obtain further medical and/or hospital care, attention, and services.

149. By reason of the foregoing, Plaintiffs Julie Williams, Randall Williams and M.C.W. have been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

FOURTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

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

151. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiff and her healthcare providers. GSK had exclusive access to material information about the

teratogenic risks of Zofran, and GSK knew that neither Plaintiff nor her medical providers could reasonably discover that information.

152. In violations of the existing standards and duties of care, GSK fraudulently concealed and intentionally omitted material facts in representations by means including, but not limited to advertisements, labeling, marketing, marketing persons, notices, product information and written and oral information provided to patients, medical providers, generic bioequivalent ANDA holders, and the FDA.

153. In violations of the existing standards and duties of care, in representations to Plaintiff's healthcare providers, expectant mothers including Plaintiff, generic bioequivalent ANDA holders 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. Independent researchers have reported in peer-reviewed literature that in utero Zofran exposure increases the risk of birth defects;

e. 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;

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

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

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

154. Defendant'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 Julie Williams into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran and/or its generic bioequivalent, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

155. Defendant's knew that physicians, hospitals, healthcare providers and expectant mothers such as Plaintiff Julie Williams had no way to determine the truth behind Defendant's concealment and material omissions of facts surrounding Zofran despite exercising reasonable diligence.

156. Plaintiff Julie Williams and her providers reasonably relied on Defendant's promotional statements concerning Zofran's asserted safety and efficacy in pregnant women, from which Defendant negligently, fraudulently and/or purposefully omitted material facts. Had GSK disclosed the material omissions about the product, Plaintiff would not have used Zofran and/or its generic bioequivalent and her providers would not have prescribed Zofran and at a minimum would have communicated to Plaintiff the pregnancy risks and how to avoid them.

157. As a direct and proximate result of the defective nature of Zofran, M.C.W. was 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 present and future medical treatment, monitoring and/or medications.

158. Plaintiffs Julie and Randall Williams also sustained severe emotional distress and suffering as a result Defendant's wrongful conduct and the injuries to their child.

159. As a direct and proximate result of the foregoing acts and omissions, M.C.W. requires 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 child will in the future be required to obtain further medical and/or hospital care, attention, and services.

160. By reason of the foregoing, Plaintiffs Julie Williams, Randall Williams and M.C.W. have been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

FIFTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

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

162. GSK had a duty to exercise reasonable care to those whom they provided product information about Zofran and to all those relying on the information provided, including Plaintiff and her healthcare providers.

163. In violation of the existing standards and duties of care, GSK materially misrepresented and omitted complete and accurate information in Zofran's labeling, advertising, marketing, sales and marketing persons, notices, oral promotional efforts, and product information concerning the nature, character, quality, safety, and proper use of their product. Specifically, these misrepresentations GSK falsely and negligently represented to the medical community and

expectant mothers, including Plaintiff and her healthcare providers, include, but are not limited to the following:

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.

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

165. Plaintiff and her providers reasonably relied upon GSK's expertise, skill, judgment, and knowledge and upon their express and/or implied warranties that their product was safe, efficacious, adequately tested, of merchantable quality and fit for use during pregnancy. In justifiable reliance upon these misrepresentations, Plaintiff and her providers were induced to prescribe and use Zofran and/or its generic bioequivalent.

166. Had GSK not made express and implied false statements, or revealed all material information about Zofran, Plaintiff's providers would not have prescribed it and Plaintiff would not have used Zofran and/or its generic bioequivalent.

167. As a result of the foregoing acts and omissions, M.C.W. has 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.

168. As a result of the foregoing acts and omissions, M.C.W. requires and will require more health care and services and did incur economic injury, including, medical,

health, incidental and related expenses. Plaintiffs Julie and Randall Williams are informed and believes and further allege that M.C.W. will in the future be required to obtain further medical and/or hospital care, attention, and services.

169. Plaintiffs Julie and Randall Williams also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to their child.

170. By reason of the foregoing, Plaintiffs have been damaged by GSK's wrongful conduct.

SIXTH CAUSE OF ACTION

(Punitive Damages)

171. Plaintiffs repeat, reiterate, and re-allege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

172. The conduct of each Defendant as set forth hereinabove showed willful misconduct, malice, fraud, wantonness, oppression or that entire want of care which would raise the presumption of a conscious indifference to consequences. Accordingly, punitive damages should be imposed against each Defendant pursuant to O.C.G.A. § 51-12-5.1 and other applicable laws, to punish and deter each Defendant from repeating or continuing such unlawful conduct.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury pursuant to the laws of Georgia and the Seventh Amendment of the U.S. Constitution.

PRAYER FOR RELIEF

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

a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

b) For medical, incidental and hospital expenses according to proof;

c) For pre-judgment and post-judgment interest as provided by law;

d) For consequential damages in excess of the jurisdictional minimum of this Court;

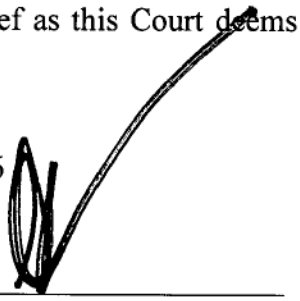
e) For compensatory damages in excess of the jurisdictional minimum of this Court;

f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;

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

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

Respectfully submitted this 9th day of March, 2016



Robert C. Buck
Georgia Bar No. 092495

BUCK LAW FIRM
ATTORNEYS AT LAW
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1050 Crown Pointe Parkway
Atlanta, Georgia 30338
(678) 338-4999 Telephone
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rbuck@buckfirm.com

SHERIFF'S ENTRY OF SERVICE — SC-85-2 — LYDS EASTERBERRY CO., COVINGTON, GA 30015

Civil Action No. 16A 02416-5

Date Filed 3-10-16

Superior Court	☑	Magistrate Court	☐
State Court	☐	Probate Court	☐
Juvenile Court	☐		

Georgia, Gwinnett COUNTY

Julie Williams and Randall Williams, Individually and as Parents and Natural Guardians of M.C.W. and M.W., a minor

Plaintiff

VS.

GlaxoSmithKline LLC

Defendant

Garnishee

Attorney's Address

Robert C. Buck
Buck Law Firm
1050 Crown Pointe Pky, Ste 940
Atlanta, GA 30338

Name and Address of Party to be Served.

GlaxoSmithKline, LLC
via Corporation Service Company
40 Technology Parkway South, Ste. 300
Norcross, GA 30092

SHERIFF'S ENTRY OF SERVICE

PERSONAL

☐ I have this day served the defendant _____ personally with a copy of the within action and summons.

NOTORIOUS

I have this day served the defendant _____ by leaving a copy of the action and summons at his most notorious place of abode in this County.

☐ Delivered same into hands of _____ described as follows: age, about _____ years; weight _____ pounds; height, about _____ feet and _____ inches, domiciled at the residence of defendant.

CORPORATION

Served the defendant Glaxo Smith Kline, LLC a corporation

☑ by leaving a copy of the within action and summons with Alicia Smith, R.A. in charge of the office and place of doing business of said Corporation in this County.

TACK & MAIL

☐ I have this day served the above styled affidavit and summons on the defendant(s) by posting a copy of the same to the door of the premises designated in said affidavit, and on the same day of such posting by depositing a true copy of same in the United States Mail, First Class in an envelope properly addressed to the defendant(s) at the address shown in said summons, with adequate postage affixed thereon containing notice to the defendant(s) to answer said summons at the place stated in the summons.

NON EST

☐ Diligent search made and defendant _____ not to be found in the jurisdiction of this Court.

This 14 day of Mar, 20 16.

J. Brown

DEPUTY

SC 337

SHERIFF DOCKET _____ PAGE _____

WHITE-CLERK CANARY-PLAINTIFF PINK-DEFENDANT

Exhibit B

3 of 3 DOCUMENTS

TOBIN v. ASTRA PHARMACEUTICAL INC

Case No. 88-0350-L(CS)

1991 Jury Verdicts LEXIS 47209; 1 Exp. Wit. 22873

PARTY NAMES: PLAINTIFF(S):
Tobin

DEFENDANT(S):
Astra Pharmaceutical Inc

TOPIC: Medical Malpractice

INJURY: Physical Injury

METHOD OF RESOLUTION: Trial

DATE: March, 1991

AWARD: $ 4,508,400

STATE: Kentucky

COURT: Usdc

CASE SUMMARY: Suffered congestive heart failure requiring heart transplant while taking yutopar to inhibit labor

AWARD DETAILS: Trial,

CASE RESOLUTION: For Plaintiff

COUNSEL: PLAINTIFF COUNSEL:
Morris, Douglas H II
FIRM NAME- Morris & Player, Pllc
ADDRESS-1211 Herr Lane Suite 205 Louisville, Kentucky 40222
PHONE- (502) 426-3430
WEBSITE- WWW.MORRISPLAYER.COM

DEFENDANT COUNSEL:
Blackburn, Winfrey P Jr.
FIRM NAME- Blackburn, Domene & Burchett
ADDRESS-614 W Main St, Ste 3000 Louisville, Kentucky 40202
PHONE- (502) 584-1600
WEBSITE- www.bdblawky.com

EXPERTS: EXPERT(S) FOR PLAINTIFF:
Waller, Dr. Bruce Frank
ADDRESS- 8333 Naab Rd Ste #400 Indianapolis, Indiana 462601992
PHONE- (317) 338-6666
SPECIALITY- Internal Medicine, Cardiovascular Diseases, Cardiovascular Pathology, Cardiology, Medicine, Anatomical Pathology
AFFILIATION- St. Vincent Hospital, Inc., The Care Group Llc, Indiana University Medical Center

VIEW OTHER AVAILABLE CONTENT RELATED TO THIS EXPERT: Waller, Bruce Frank

24 Nat. J.V.R.A. 7:C1, 1000 WL 177472 (Pa.Com.Pl.) (Verdict and Settlement Summary)

Court of Common Pleas of Pennsylvania, Forty-fifth Judicial District, Lackawanna County.

WHITE vs. **BEHLKE** ET AL.

n/a
DATE OF VERDICT/SETTLEMENT: No Date Given
TOPIC: MEDICAL MALPRACTICE - DELAY IN PERFORMANCE OF CAESAREAN SECTION - NEGLIGENT INDUCTION OF LABOR - OXYGEN DEPRIVATION TO FETUS - PERMANENT BRAIN DAMAGE - CEREBRAL PALSY - 24-HOUR ATTENDANT CARE REQUIRED.

SUMMARY:
Result: $20,500,000 VERDICT

ATTORNEY:
Plaintiff's: Jeffrey M. Kornblau and Lynn Sare Kornblau of Kornblau & Kornblau in Jenkintown, PA.
Defendant's: obstetrician and his medical group: Eugene P. Feeney of Weber, Gallagher, Simpson, Stapleton, Fires & Newby in Scranton, PA.
Defendant's: hospital: Michael P. Perry of O'Malley, Harris, Durkin & Perry in Scranton, PA.
JUDGE: Terrence R. Nealon

RANGE AMOUNT: $5,000,000-999,999,999

STATE: Pennsylvania
COUNTY: Lackawanna

INJURIES:
MEDICAL MALPRACTICE - DELAY IN PERFORMANCE OF CAESAREAN SECTION - NEGLIGENT INDUCTION OF LABOR - OXYGEN DEPRIVATION TO FETUS - PERMANENT BRAIN DAMAGE - CEREBRAL PALSY - 24-HOUR ATTENDANT CARE REQUIRED.

FACTS:
The plaintiffs alleged that the defendants, which included an obstetrician, his practice group and a hospital, were responsible for the permanent brain damage suffered by their newborn son in 2001. The plaintiffs contended that the defendant obstetrician failed to perform an immediate Caesarean section and negligently attempted to induce labor with Pitocin, causing oxygen deprivation to the fetus for a period of more than four hours. The plaintiff also claimed that hospital nurses failed to fully apprise the doctor of the plaintiff's medical condition. The defendants denied negligence and maintained that the baby's brain injury resulted from a fetal maternal hemorrhage which was beyond their control. The plaintiff mother testified that she telephoned her treating obstetrician on June 30, 2001, and reported decreased fetal movement. The plaintiff was due to deliver the baby in July. The plaintiff was instructed to go to the defendant hospital's out-

patient labor and delivery triage area and records showed that she arrived there at 2:35 p.m. The plaintiff was connected to a fetal monitor which the plaintiff's experts contended showed abnormalities, including decreased or absent variability. The defendant obstetrician was covering at the hospital on the day in question and was called by a hospital nurse. The plaintiff alleged that the defendant hospital's nurse failed to correctly communicate the plaintiff's condition and failed to make timely nursing interventions. The defendant physician, who was in the hospital, did not see the plaintiff mother for more than two

hours after being called and the plaintiff claimed that he failed to urgently order a biophysical profile. Even after the biophysical profile was ordered, the plaintiff claimed that the nurses failed to have the testing performed on a STAT basis.

The plaintiff's expert obstetrician testified that the clinical presentation, non-reactive fetal monitor strip and biophysical profile demonstrated a lack of oxygen to the fetus which required the performance of an immediate Caesarean section. However, the plaintiffs alleged that instead of performing the Caesarean section, the defendant doctor negligently elected to induce labor with administration of Pitocin. The plaintiff also claimed that the hospital nurses were negligent for failing to administer oxygen, failing to correctly interpret the fetal monitoring strips and failing to question the defendant doctor's order for induction of labor. The plaintiff's experts testified that the fetus was suffering blood loss across the placenta due to fetal maternal hemorrhage and that the administration of the Pitocin caused a greater decrease in the amount of blood and oxygen reaching the fetus. The Pitocin caused the fetal heart rate to drop and created further stress on the unborn fetus, according to the plaintiff's claims. An emergency Caesarean section was called approximately four and a-half hours after the plaintiff's presentation to the 373 hospital. By that time, the plaintiff alleged that the baby had already suffered severe brain damage as a result of prolonged oxygen deprivation. The baby's APGAR scores were zero at birth, but he was resuscitated after an effort which lasted ten minutes.

The minor plaintiff was seven years old at the time of trial, but was estimated to be functioning at the level of a six-to-nine-

month-old infant. The jury viewed a "Day In The Life" film depicting the boy's routine activities. He has been diagnosed with permanent brain damage and cerebral palsy. The minor plaintiff is unable to use his arms, walk, talk or see. He has no control of his body functions and is confined to a wheelchair. The plaintiff's doctors testified that minor plaintiff will never be able to live independently and will require round-the-clock care for the remainder of his normal life expectancy.

The defendants disputed that the clinical presentation, fetal monitor strips or biophysical profile demonstrated fetal distress sufficient to warrant performance of a Caesarean section during the time in question. The defendant testified that he did not order the Pitocin to induce labor, but was merely using the Pitocin for a contraction stress test. The defendants argued that the Caesarean section was called and performed as soon as warranted. The defendants also argued that the fetus had already suffered extensive brain damage as a result of the fetal maternal hemorrhage prior to the plaintiff mother coming to the hospital. By a vote of 11-to-1, the jury found the defendant obstetrician 60% negligent and the co-defendant hospital 40% negligent. The plaintiffs were awarded $20.5 million in damages, including $2 million to the plaintiff parents for their son's medical expenses until age 18 and $18.5 million in damages to the minor plaintiff when he turns age 18. Post-trial motions are currently pending.

Jury Verdicts Review Publications, Inc.

PUBLISHED IN: National Jury Verdict Review & Analysis, Vol. 24, Issue 7

End of Document

22 Nat. J.V.R.A. 10:C3, 2007 WL 7952305 (Fla.Cir.Ct.) (Verdict and Settlement Summary)

Florida Circuit Court, Thirteenth Judicial Circuit, Hillsborough County.

ESTRADA vs. UNIVERSITY OF SOUTH FLORIDA

06-000625
DATE OF VERDICT/SETTLEMENT: July 23, 2007
TOPIC: WRONGFUL BIRTH - FAILURE TO DIAGNOSE SMITH-LEMLI OPITZ SYNDROME IN FIRST BORN - PARENTS NEGLIGENTLY ADVISED THAT CONDITION WAS NOT GENETIC - SECOND CHILD BORN WITH SAME DISORDER - INABILITY TO WALK - GASTROINTESTINAL FEEDING TUBE REQUIRED - LIFE-LONG ATTENDANT CARE NEEDED.

SUMMARY:
Result: $23,553,000 GROSS VERDICT

EXPERT WITNESSES:
Plaintiff's geneticist expert: Robert Steiner from Portland, OR.
Plaintiff's physiatrist expert: Craig Lichtblau from West Palm Beach, FL.
Plaintiff's rehabilitation expert: Larry Forman from Miami, FL.
Plaintiffs' economist expert: Patricia Pacey from Boulder, Co.
Defendant's geneticist expert:
ATTORNEY:
Plaintiff's: Chris Searcy and John Shipley of Searcy, Denney, Scarola, Barnhart & Shipley in West Palm Beach, FL.
Defendant's: Janice Merrill of Janice Merrill, P.A., in Longwood, FL.
JUDGE: William Levens

RANGE AMOUNT: $5,000,000-999,999,999

STATE: Florida
COUNTY: Hillsborough

INJURIES:
WRONGFUL BIRTH - FAILURE TO DIAGNOSE SMITH-LEMLI OPITZ SYNDROME IN FIRST BORN - PARENTS NEGLIGENTLY ADVISED THAT CONDITION WAS NOT GENETIC - SECOND CHILD BORN WITH SAME DISORDER - INABILITY TO WALK - GASTROINTESTINAL FEEDING TUBE REQUIRED - LIFE-LONG ATTENDANT CARE NEEDED.

FACTS:
This was a "wrongful birth" action brought by the parents of a child born with Smith-Lemli-Opitz Syndrome, a debilitating genetic condition. The plaintiffs claimed that a physician, employed by the defendant, University of South Florida, negligently failed to diagnose the disorder in the plaintiffs' first born son. The plaintiffs contended that the defendant's employee also negligently advised the plaintiff parents that the first born child's problems were not genetic, resulting in the "wrongful birth" of a second son with Smith-

Lemli-Opitz Syndrome. The defendant stipulated to negligence in failing to diagnose the syndrome and in telling the plaintiff parents that the condition was not genetic. The defense maintained that another physician was also partially responsible for the missed diagnosis. The other physician was listed as a Fabre defendant on the verdict form.

The plaintiffs sought advice from the defendant's genetics department after their oldest son was born with dysmorphic features that they thought could be genetically linked. The plaintiffs contended that the head of the defendant's genetics department, failed to diagnose Smith-Lemli-Opitz Syndrome in their oldest son. Smith-Lemli-Opitz Syndrome is an autosomal recessive genetic disorder with characteristics including, sexual ambiguity, fusion of the second and third toes (syndactylism), inability to talk, difficulty ambulating, refusal to take food by mouth, autism, club feet, low-set ears and odd facial features.

Testimony established that the defendant's geneticist advised the plaintiffs that their oldest son's problems were not genetic and that they had no greater chance of having a reoccurrence than the general population. In fact, the plaintiff's expert testified that Smith-Lemli-Opitz Syndrome is genetically linked and the plaintiffs actually had a 25% possibility that any future offspring would also be born with the same condition. The plaintiffs' second son, Caleb, was born two years and five months after their first son. He was diagnosed with Smith-Lemli-Opitz Syndrome shortly after birth, based in part on the fusion of his second and third toes. The plaintiff mother, a veterinary cardiology professor, had fetal ultrasound on every prenatal visit. Due to ambiguous genitalia (a hallmark of the Smith-Lemli-

Opitz Syndrome) her ob/gyn thought that the fetus was female.

The second son, Caleb, was four years old at trial. He is unable to walk and is fed through a gastrointestinal tube. Caleb was carried to court by his parents to appear for trial. The plaintiff's experts testified that Caleb will never be able to live independently, will have a normal life expectancy and will require permanent attendant care. The plaintiff also introduced a " Day in the Life" film depicting Caleb's daily activities including crawling on the floor and being fed through a tube.

The defendant argued that another physician, a geneticist, was also responsible for failing to diagnose the Smith-Lemli-Opitz Syndrome in the oldest child. This physician saw the first born son once at an early learning center (before Caleb was born) and suspected Smith-Lemli-Opitz Syndrome; yet, she did not follow-up on her suspicions.

The jury found the defendant 90% negligent and the Fabre defendant ten percent negligent. The plaintiffs were awarded $23,553,000 in damages which was reduced to a net award of $21,197,700. The award included $53,000 in past medical expenses; $18,500,000 in future medical expenses; $2.5 million for the plaintiff mother's mental anguish; and $2.5 million for the plaintiff father's mental anguish. The case is currently on appeal.

Jury Verdicts Review Publications, Inc.

PUBLISHED IN: National Jury Verdict Review & Analysis, Vol. 22, Issue 10

End of Document

JS44 (Rev. 1/14 NDGA)

CIVIL COVER SHEET

The JS44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form is required for the use of the Clerk of Court for the purpose of initiating the civil docket record. (SEE INSTRUCTIONS ATTACHED)

I. (a) PLAINTIFF(S)

Julie Williams and Randall Williams, Individually and as Parents and Natural Guardians of M.C.W., a Minor

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Gwinnett County, Georgia
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANT(S)

GlaxoSmithKline LLC

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT New Castle, Delaware
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, TELEPHONE NUMBER, AND E-MAIL ADDRESS)

Robert C. Buck
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II. BASIS OF JURISDICTION

(PLACE AN "X" IN ONE BOX ONLY)

- ☐ 1 U.S. GOVERNMENT PLAINTIFF
- ☐ 2 U.S. GOVERNMENT DEFENDANT
- ☐ 3 FEDERAL QUESTION (U.S. GOVERNMENT NOT A PARTY)
- ■ 4 DIVERSITY (INDICATE CITIZENSHIP OF PARTIES IN ITEM III)

III. CITIZENSHIP OF PRINCIPAL PARTIES

(PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)
(FOR DIVERSITY CASES ONLY)

PLF	DEF		PLF	DEF	
■ 1	☐ 1	CITIZEN OF THIS STATE	☐ 4	☐ 4	INCORPORATED OR PRINCIPAL PLACE OF BUSINESS IN THIS STATE
☐ 2	■ 2	CITIZEN OF ANOTHER STATE	☐ 5	☐ 5	INCORPORATED AND PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE
☐ 3	☐ 3	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	☐ 6	☐ 6	FOREIGN NATION

IV. ORIGIN

(PLACE AN "X "IN ONE BOX ONLY)

- ☐ 1 ORIGINAL PROCEEDING
- ■ 2 REMOVED FROM STATE COURT
- ☐ 3 REMANDED FROM APPELLATE COURT
- ☐ 4 REINSTATED OR REOPENED
- ☐ 5 TRANSFERRED FROM ANOTHER DISTRICT (Specify District)
- ☐ 6 MULTIDISTRICT LITIGATION
- ☐ 7 APPEAL TO DISTRICT JUDGE FROM MAGISTRATE JUDGE JUDGMENT

V. CAUSE OF ACTION

(CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE - DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

28 U.S.C. Sections 1332, 1441, and 1446.
Plaintiffs allege injuries as a result of the phamaceutical product, Zofran.

(IF COMPLEX, CHECK REASON BELOW)

- ☐ 1. Unusually large number of parties.
- ☐ 2. Unusually large number of claims or defenses.
- ■ 3. Factual issues are exceptionally complex
- ■ 4. Greater than normal volume of evidence.
- ■ 5. Extended discovery period is needed.
- ☐ 6. Problems locating or preserving evidence
- ☐ 7. Pending parallel investigations or actions by government.
- ■ 8. Multiple use of experts.
- ☐ 9. Need for discovery outside United States boundaries.
- ■ 10. Existence of highly technical issues and proof.

CONTINUED ON REVERSE

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT $_____ APPLYING IFP _____ MAG. JUDGE (IFP)_____

JUDGE_____ MAG. JUDGE_____ NATURE OF SUIT_____ CAUSE OF ACTION_____
(Referral)

VI. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT - "0" MONTHS DISCOVERY TRACK
- ☐ 150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT
- ☐ 152 RECOVERY OF DEFAULTED STUDENT LOANS (Excl. Veterans)
- ☐ 153 RECOVERY OF OVERPAYMENT OF VETERAN'S BENEFITS

CONTRACT - "4" MONTHS DISCOVERY TRACK
- ☐ 110 INSURANCE
- ☐ 120 MARINE
- ☐ 130 MILLER ACT
- ☐ 140 NEGOTIABLE INSTRUMENT
- ☐ 151 MEDICARE ACT
- ☐ 160 STOCKHOLDERS' SUITS
- ☐ 190 OTHER CONTRACT
- ☐ 195 CONTRACT PRODUCT LIABILITY
- ☐ 196 FRANCHISE

REAL PROPERTY - "4" MONTHS DISCOVERY TRACK
- ☐ 210 LAND CONDEMNATION
- ☐ 220 FORECLOSURE
- ☐ 230 RENT LEASE & EJECTMENT
- ☐ 240 TORTS TO LAND
- ☐ 245 TORT PRODUCT LIABILITY
- ☐ 290 ALL OTHER REAL PROPERTY

TORTS - PERSONAL INJURY - "4" MONTHS DISCOVERY TRACK
- ☐ 310 AIRPLANE
- ☐ 315 AIRPLANE PRODUCT LIABILITY
- ☐ 320 ASSAULT, LIBEL & SLANDER
- ☐ 330 FEDERAL EMPLOYERS' LIABILITY
- ☐ 340 MARINE
- ☐ 345 MARINE PRODUCT LIABILITY
- ☐ 350 MOTOR VEHICLE
- ☐ 355 MOTOR VEHICLE PRODUCT LIABILITY
- ☐ 360 OTHER PERSONAL INJURY
- ☐ 362 PERSONAL INJURY - MEDICAL MALPRACTICE
- ☐ 365 PERSONAL INJURY - PRODUCT LIABILITY
- ☑ 367 PERSONAL INJURY - HEALTH CARE/ PHARMACEUTICAL PRODUCT LIABILITY
- ☐ 368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY

TORTS - PERSONAL PROPERTY - "4" MONTHS DISCOVERY TRACK
- ☐ 370 OTHER FRAUD
- ☐ 371 TRUTH IN LENDING
- ☐ 380 OTHER PERSONAL PROPERTY DAMAGE
- ☐ 385 PROPERTY DAMAGE PRODUCT LIABILITY

BANKRUPTCY - "0" MONTHS DISCOVERY TRACK
- ☐ 422 APPEAL 28 USC 158
- ☐ 423 WITHDRAWAL 28 USC 157

CIVIL RIGHTS - "4" MONTHS DISCOVERY TRACK
- ☐ 441 VOTING
- ☐ 442 EMPLOYMENT
- ☐ 443 HOUSING/ ACCOMMODATIONS
- ☐ 444 WELFARE
- ☐ 440 OTHER CIVIL RIGHTS
- ☐ 445 AMERICANS with DISABILITIES - Employment
- ☐ 446 AMERICANS with DISABILITIES - Other
- ☐ 448 EDUCATION

IMMIGRATION - "0" MONTHS DISCOVERY TRACK
- ☐ 462 NATURALIZATION APPLICATION
- ☐ 465 OTHER IMMIGRATION ACTIONS

PRISONER PETITIONS - "0" MONTHS DISCOVERY TRACK
- ☐ 463 HABEAS CORPUS- Alien Detainee
- ☐ 510 MOTIONS TO VACATE SENTENCE
- ☐ 530 HABEAS CORPUS
- ☐ 535 HABEAS CORPUS DEATH PENALTY
- ☐ 540 MANDAMUS & OTHER
- ☐ 550 CIVIL RIGHTS - Filed Pro se
- ☐ 555 PRISON CONDITION(S) - Filed Pro se
- ☐ 560 CIVIL DETAINEE: CONDITIONS OF CONFINEMENT

PRISONER PETITIONS - "4" MONTHS DISCOVERY TRACK
- ☐ 550 CIVIL RIGHTS - Filed by Counsel
- ☐ 555 PRISON CONDITION(S) - Filed by Counsel

FORFEITURE/PENALTY - "4" MONTHS DISCOVERY TRACK
- ☐ 625 DRUG RELATED SEIZURE OF PROPERTY 21 USC 881
- ☐ 690 OTHER

LABOR - "4" MONTHS DISCOVERY TRACK
- ☐ 710 FAIR LABOR STANDARDS ACT
- ☐ 720 LABOR/MGMT. RELATIONS
- ☐ 740 RAILWAY LABOR ACT
- ☐ 751 FAMILY and MEDICAL LEAVE ACT
- ☐ 790 OTHER LABOR LITIGATION
- ☐ 791 EMPL. RET. INC. SECURITY ACT

PROPERTY RIGHTS - "4" MONTHS DISCOVERY TRACK
- ☐ 820 COPYRIGHTS
- ☐ 840 TRADEMARK

PROPERTY RIGHTS - "8" MONTHS DISCOVERY TRACK
- ☐ 830 PATENT

SOCIAL SECURITY - "0" MONTHS DISCOVERY TRACK
- ☐ 861 HIA (1395ff)
- ☐ 862 BLACK LUNG (923)
- ☐ 863 DIWC (405(g))
- ☐ 863 DIWW (405(g))
- ☐ 864 SSID TITLE XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS - "4" MONTHS DISCOVERY TRACK
- ☐ 870 TAXES (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - THIRD PARTY 26 USC 7609

OTHER STATUTES - "4" MONTHS DISCOVERY TRACK
- ☐ 375 FALSE CLAIMS ACT
- ☐ 376 QUI TAM 31 USC 3729(a)
- ☐ 400 STATE REAPPORTIONMENT
- ☐ 430 BANKS AND BANKING
- ☐ 450 COMMERCE/ICC RATES/ETC.
- ☐ 460 DEPORTATION
- ☐ 470 RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS
- ☐ 480 CONSUMER CREDIT
- ☐ 490 CABLE/SATELLITE TV
- ☐ 890 OTHER STATUTORY ACTIONS
- ☐ 891 AGRICULTURAL ACTS
- ☐ 893 ENVIRONMENTAL MATTERS
- ☐ 895 FREEDOM OF INFORMATION ACT
- ☐ 899 ADMINISTRATIVE PROCEDURES ACT / REVIEW OR APPEAL OF AGENCY DECISION
- ☐ 950 CONSTITUTIONALITY OF STATE STATUTES

OTHER STATUTES - "8" MONTHS DISCOVERY TRACK
- ☐ 410 ANTITRUST
- ☐ 850 SECURITIES / COMMODITIES / EXCHANGE

OTHER STATUTES - "0" MONTHS DISCOVERY TRACK
- ☐ 896 ARBITRATION (Confirm / Vacate / Order / Modify)

*** PLEASE NOTE DISCOVERY TRACK FOR EACH CASE TYPE. SEE LOCAL RULE 26.3**

VII. REQUESTED IN COMPLAINT:

☐ **CHECK IF CLASS ACTION UNDER F.R.Civ.P. 23** **DEMAND $**_____

JURY DEMAND ■ **YES** ☐ **NO (CHECK YES ONLY IF DEMANDED IN COMPLAINT)**

VIII. RELATED/REFILED CASE(S) IF ANY

JUDGE F. Dennis Saylor, IV **DOCKET NO.** 1:15-md-02657-FDS (D. Mass.)

CIVIL CASES ARE DEEMED RELATED IF THE PENDING CASE INVOLVES: (CHECK APPROPRIATE BOX)

- ☐ **1. PROPERTY INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.**
- ■ **2. SAME ISSUE OF FACT OR ARISES OUT OF THE SAME EVENT OR TRANSACTION INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.**
- ☐ **3. VALIDITY OR INFRINGEMENT OF THE SAME PATENT, COPYRIGHT OR TRADEMARK INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.**
- ☐ **4. APPEALS ARISING OUT OF THE SAME BANKRUPTCY CASE AND ANY CASE RELATED THERETO WHICH HAVE BEEN DECIDED BY THE SAME BANKRUPTCY JUDGE.**
- ☐ **5. REPETITIVE CASES FILED BY PRO SE LITIGANTS.**
- ☐ **6. COMPANION OR RELATED CASE TO CASE(S) BEING SIMULTANEOUSLY FILED (INCLUDE ABBREVIATED STYLE OF OTHER CASE(S)):**
- ☐ **7. EITHER SAME OR ALL OF THE PARTIES AND ISSUES IN THIS CASE WERE PREVIOUSLY INVOLVED IN CASE NO. , WHICH WAS DISMISSED. This case ☐ IS ☐ IS NOT (check one box) SUBSTANTIALLY THE SAME CASE.**

/s/ Leonard Searcy, II 4/12/16

SIGNATURE OF ATTORNEY OF RECORD **DATE**