

1 Wendy R. Fleishman
wfleishman@lchb.com
2 LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
3 New York, NY 10013-1413
Telephone: (212) 355-9500
4 Facsimile: (212) 355-9592

5 Elizabeth J. Cabraser
ecabraser@lchb.com
6 Sarah R. London
slondon@lchb.com
7 LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
8 San Francisco, CA 94111-3339
Telephone: 415.956.1000
9 Facsimile: 415.956.1008

10 Attorneys for Plaintiffs

11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA
13

14 KATHERINE MURRAY and MATTHEW
15 MURRAY, Individually, and on Behalf of
Minor J.M.,

16 Plaintiffs,

17 v.

18 GLAXOSMITHKLINE LLC,

19 Defendant.
20
21
22

Case No.

COMPLAINT FOR DAMAGES

- (1) Negligence;
- (2) Negligence Per Se;
- (3) Strict Products Liability;
- (4) Intentional Misrepresentation;
- (5) Concealment;
- (6) Negligent Misrepresentation;
- (7) Breach Of Express Warranty;
- (8) Breach Of Implied Warranty;
- (9) Violation Of Cal. Bus. & Prof. Code §§ 17200, *Et Seq.* And 17500 *Et Seq.*; and
- (10) Violations Of Deceptive Trade Practices And Consumer Protection Act, M.G.L. c. 93A.

JURY DEMAND

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26 **COMPLAINT AND JURY DEMAND**

27 COMES NOW Plaintiffs, Katherine and Matthew Murray, individually and on behalf of
28 their daughter, J.M., a minor (“Plaintiffs”), who by and through the undersigned counsel hereby

1 submit this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline
2 (“GSK” or “Defendant”) for compensatory and punitive damages, equitable relief, and such other
3 relief deemed just and proper arising from the injuries to J.M. as a result of Ms. Murray’s prenatal
4 exposures to the prescription drug Zofran® (ondansetron hydrochloride), also marketed in its
5 generic form as ondansetron. In support of this Complaint, Plaintiffs allege the following:

6
7 **I. INTRODUCTION**

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

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

13 3. Although the only FDA approval for this drug was for seriously ill patients, GSK
14 marketed Zofran “off-label” as a safe and effective treatment for the very common side effect of a
15 normal pregnancy – pregnancy-related nausea and vomiting – otherwise known as “morning
16 sickness.” GSK did this despite having knowledge that such representations were utterly false, as
17 GSK had never once undertaken a single clinical study to examine the safety and effects of this
18 powerful drug on a pregnant mother or her growing child in utero. Unlike another anti-nausea
19 prescription drug available on the market – which is FDA-approved in the United States for
20 treating morning sickness in pregnant women –GSK simply chose not to study Zofran in pregnant
21 women or seek FDA approval to market the drug for treatment during pregnancy. GSK avoided
22 conducting these studies, because the delay occasioned by undertaking the studies would have
23 hampered its marketing of Zofran® and decreased profits by potentially linking the drug to
24 serious birth defects. GSK’s conduct was in violation of the FDA’s regulations, which are
25 intended to protect the public health by assuring safety, efficacy and security of drugs, among
26 others things, used on adults and children, including those in utero.
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1 4. As a result of GSK's fraudulent marketing campaign, Zofran® was prescribed by
2 unknowing doctors who placed the drug into the hands of unsuspecting pregnant women
3 throughout the United States. These women ingested the drug because they innocently believed
4 that Zofran® was an appropriate drug for use in their circumstance. When they ingested the drug,
5 these pregnant women had no way of knowing that Zofran® had never been studied in pregnant
6 women, much less shown to be a safe and effective treatment for pregnancy-related nausea.

7
8 5. By contrast, GSK knew that Zofran® was unsafe for ingestion by expectant
9 mothers. In the 1980s, GSK conducted animal studies which revealed evidence of toxicity,
10 intrauterine deaths and malformations in offspring, and further showed that Zofran's active
11 ingredient transferred through the placental barrier in pregnant mammals to their fetuses. A later
12 study conducted in humans confirmed that ingested Zofran® readily crossed the human placenta
13 barrier and exposed fetuses to substantial concentrations. GSK did not disclose this information
14 to pregnant women or their physicians.

15
16 6. In 1992, GSK began receiving mounting evidence of reports of birth defects
17 associated with the use of Zofran®. GSK had received at least 32 such reports by 2000, and has
18 received more than 200 such reports to date. GSK never disclosed these reports to pregnant
19 women or their physicians.

20
21 7. In addition, scientists have conducted large-scale epidemiological studies that have
22 demonstrated an elevated risk of developing birth defects such as those suffered in this case.
23 GSK has not disclosed this to pregnant women or their physicians. Instead, GSK sales
24 representatives specifically marketed and promoted Zofran® as a morning sickness drug
25 throughout the relevant time periods discussed herein.

1 8. In 2012, GSK pled guilty to criminal charges lodged by the United States of
2 America, through the Department of Justice, for its “off-label” promotion of its drugs for uses
3 never approved by the FDA.

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

7 10. GSK’s written agreement with the United States reports GSK’s settlement of
8 claims that GSK:

- 9
- 10 a. **“promoted the sale and use of Zofran for a variety of conditions other**
 - 11 **than those for which its use was approved as safe and effective by the**
 - 12 **FDA (including hyperemesis and pregnancy-related nausea)”**
 - 13 b. **“made and/or disseminated unsubstantiated and false representations**
 - 14 **about the safety and efficacy of Zofran concerning the uses described**
 - 15 **in subsection (a) [hyperemesis and pregnancy-related nausea]”**
 - 16 c. **“offered and paid illegal remuneration to health care professionals to**
 - 17 **induce them to promote and prescribe Zofran”**

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

18 11. GSK’s conduct has caused devastating, irreversible, and life-long consequences
19 and suffering to innocent newborns and their families, like Plaintiffs herein.

20 12. Plaintiffs’ minor child, J.M., was born in 2007 with congenital heart defects after
21 her mother, Ms. Murray, began taking Zofran, beginning in her first trimester of pregnancy to
22 alleviate the symptoms of morning sickness.

23 13. J.M. was born with severe congenital heart malformations as a direct and
24 proximate result of her prenatal exposures to Zofran. In particular, J.M. was born with an atrial
25 septal defect. As a result of these injuries, J.M. underwent a cardiac catheterization and
26 placement of a septal occluder when she was only four years old. Further, J.M. will require more
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1 constant and continuous medical monitoring and treatment than had she not been exposed to
2 Zofran.

3 14. J.M was exposed to Zofran *in utero* during the periods when each of affected
4 tissues was forming and susceptible to developmental insult from environmental exposure.

5 15. There is no known genetic cause for J.M.'s condition. There exists no family
6 history for the condition from which J.M. suffers.

7 16. Ms. Murray was unaware of the dangerousness of Zofran or the fraudulent nature
8 of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during
9 pregnancy.

10 17. Had Ms. Murray known the truth about Zofran's unreasonable risk of harm, long
11 concealed by GSK, she would never have taken Zofran, and her child would never had been
12 injured as described herein.

13 18. Plaintiffs bring claims for compensatory and punitive damages, as well as
14 equitable relief in an effort to ensure that similarly situated mothers-to-be are fully informed
15 about the risks, benefits and alternatives attending drugs marketed for use in pregnant women,
16 and such other relief deemed just and proper arising from injuries and birth defects as a result of
17 exposure to Zofran.

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21 **II. JURISDICTION AND VENUE**

22 19. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because
23 the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because GSK
24 is a citizen of a state other than the state in which Plaintiffs are domiciled.

25 20. Venue in this judicial district is proper under 28 U.S.C. § 1391 inasmuch as a
26 substantial part of the events or omissions giving rise to the claims occurred in this district.
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1 21. At all times herein mentioned, GSK conducted, and continues to conduct, a
2 substantial amount of business activity and has committed a tort, in whole or in part, in this
3 judicial district. GSK is registered to conduct business in this district, and engaged in interstate
4 commerce when they advertised, promoted, supplied, and sold pharmaceutical products,
5 including Zofran, to distributors and retailers for resale to physicians, hospitals, medical
6 practitioners, and the general public, deriving substantial revenue in this district.
7

8 **III. INTRADISTRICT ASSIGNMENT**

9 22. Pursuant to Local Rule 3-5(b) and (d), assignment to the San Francisco Division is
10 proper, because a substantial part of the events or omissions giving rise to the claims occurred in
11 this division.
12

13 **IV. PARTIES**

14 23. Mr. and Ms. Murray, husband and wife, are the mother and father and natural
15 guardians of J.M., who lives with them. Mr. and Ms. Murray bring claims individually and on
16 behalf of J.M. Plaintiffs are domiciled in Alameda County in the State of California.
17

18 24. GSK is a limited liability company organized under the laws of the State of
19 Delaware. GSK's sole member is GlaxoSmithKline Holdings, Inc., which is a Delaware
20 corporation, and which has identified its principal place of business in Wilmington, Delaware.
21

22 25. GSK is the successor in interest to Glaxo, Inc. and Glaxo Wellcome Inc. Glaxo,
23 Inc. was the sponsor of the original New Drug Application ("NDA") for Zofran. Glaxo, Inc.,
24 through its division Cerenex Pharmaceuticals, authored the original package insert and labeling
25 for Zofran, including warnings and precautions attendant to its use. Glaxo Wellcome Inc.
26 sponsored additional NDAs for Zofran, monitored and evaluated post-market adverse event
27 reports arising from Zofran, and authored product labeling for Zofran. The term GSK used herein
28 refers to GSK, its predecessors Glaxo, Inc. and Glaxo Wellcome Inc., and other GSK

1 predecessors and/or affiliates that discovery reveals were involved in the testing, development,
2 manufacture, marketing, sale and/or distribution of Zofran.

3 26. At all relevant times, GSK conducted business in the State of California and has
4 derived substantial revenue from products, including Zofran, sold in this State.

5
6 **V. PERTINENT BACKGROUND ON ZOFRAN**

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

10 **INDICATIONS AND USAGE**

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

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

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

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

22 30. Although 5-hydroxytryptamine (5HT) occurs in most tissues of the human body,
23 Zofran is believed to block the effect of serotonin at the 5HT₃ receptors located along vagal
24 afferents in the gastrointestinal tract and at the receptors located in the area postrema of the
25 central nervous system (the structure in the brain that controls vomiting). Put differently, Zofran
26 antagonizes, or inhibits, the body's serotonin activity, which triggers nausea and vomiting.
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1 31. Since before GSK began selling Zofran, GSK has known that serotonin also
2 regulates developmental processes that are critical to normal embryonic development. Impeding
3 serotonin signaling during embryonic development can increase the risk of developmental insult
4 to the body's tissues that depend on uninhibited serotonin signaling, including the heart.

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

10 33. Zofran is available as an injection (2 mg/mL), a premixed injection (32 mg/50ml
11 and 4 mg/50 ml), oral tablets (4 mg, 8 mg and 24 mg); orally disintegrating tablets (4 mg and 8
12 mg) and an oral solution (4 mg/5 mL).

13
14 34. More specifically, GSK has obtained FDA approval for the following formations
15 of Zofran:

- 16 a. NDA 20-007 – Zofran Injection (FDA approved January 4, 1991)
- 17 b. NDA 20-103 – Zofran Tablets (FDA approved December 31, 1992)
- 18 c. NDA 20-403 – Zofran Premixed Injection (FDA approved January 31,
19 1995)
- 20 d. NDA 20-605 – Zofran Oral Solution (FDA approved January 24, 1997)
- 21 e. NDA 20-781 – Zofran (a/k/a Zofran-Zydis) Orally Disintegrating Tablets
22 (FDA approved January 27, 1999)

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

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

1 37. A team of the FDA’s physicians, statisticians, chemists, pharmacologists,
2 microbiologists and other scientists would then have an opportunity to: (a) review the company’s
3 data and evidence supporting its request for approval to market the drug; and (b) determine
4 whether to approve the company’s request to market the drug in the manner requested. Without
5 first obtaining approval to market a drug for the treatment of pregnant women, a pharmaceutical
6 company may not legally market its drug for that purpose.
7

8 38. GSK has not performed any clinical studies of Zofran use in pregnant women.
9 GSK, however, had the resources and know-how to perform such studies, and such studies were
10 performed to support another prescription drug that, unlike Zofran, is FDA-approved for the
11 treatment of morning sickness.
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13 39. GSK also has not submitted to the FDA any data demonstrating the safety or
14 efficacy of Zofran for treating morning sickness in pregnant women. Instead, GSK has illegally
15 circumvented the FDA-approval process by marketing Zofran for the treatment of morning
16 sickness in pregnant women without applying for the FDA’s approval to market Zofran to treat
17 that condition or any other condition in pregnant women. This practice is known as “off-label”
18 promotion, and in this case it constitutes fraudulent marketing.
19

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

23 A. **GSK’s Knowledge That Zofran Presents an Unreasonable Risk of Harm to**
24 **Babies Who Are Exposed to It During Pregnancy**

25 1. **Preclinical Studies**

26 41. Since at least the 1980s, when GSK received the results of the preclinical studies
27 that it submitted in support of Zofran’s NDA 20-007, GSK has known of the risk that Zofran
28 ingested during pregnancy in mammals crosses the placental barrier to expose the fetus to the

1 drug. For example, at least as early as the mid-1980s, GSK performed placental-transfer studies
2 of Zofran in rats and rabbits, and reported that the rat and rabbit fetuses were exposed prenatally
3 to Zofran during pregnancy.

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

9 43. GSK reported four animal studies in support of its application for approval of
10 NDA 20-0007: (1) Study No. R10937 I.V. Segment II teratological study of rats; (2) Study No.
11 R10873 I.V. Segment II teratological study of rabbits; (3) Study No. R10590 Oral Segment II
12 teratological study of rats; (4) Study No. L10649 Oral Segment II teratological study of rabbits.
13 These preclinical teratogenicity studies in rats and rabbits were stated by the sponsor, GSK, to
14 show no harm to the fetus, but the data also revealed clinical signs of toxicity, premature births,
15 intrauterine fetal deaths, and impairment of ossification (incomplete bone growth).

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

22 45. Study No. R10873 was a Segment II teratological study of pregnant rabbits
23 exposed to Zofran injection solution. Four groups of 15 pregnant rabbits (60 total) were
24 reportedly given Zofran doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. In this study, there
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1 was a reported increase in the number of intra-uterine deaths in the 4 mg/kg group versus lower-
2 dose groups. The study also reported maternal weight loss in the exposed groups.

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

5
6 46. Study No. R10590 Oral Segment II teratological study of rats. Four groups of 30
7 pregnant rats (120 total) were given Zofran orally at doses of 0, 1, 4 and 15 mg/kg/day,
8 respectively. Subdued behavior, labored breathing, which is a symptom of congenital heart
9 defects, and dilated pupils were observed in the 15 mg/kg/day group. Body weight, gestational
10 duration and fetal examinations were reported as normal, but “slight retardation in skeletal
11 ossification” was noted in the offspring.

12
13 47. Study No. L10649 Oral Segment II teratological study of rabbits. Four groups of
14 14-18 pregnant rabbits (56-64 total) were given Zofran orally at doses of 0, 1, 5.5 and 30
15 mg/kg/day. The study reported lower maternal weight gain in all of the exposed groups, as well
16 as premature delivery and “total litter loss,” referring to fetal deaths during pregnancy in the 5.5
17 mg/kg/day group. Examination of the fetuses showed “slight developmental retardation as
18 evident by incomplete ossification or asymmetry of skeleton.”

19
20 48. Even if animal studies do not reveal evidence of harm to a prenatally exposed
21 fetus, that result is not necessarily predictive of human response. For example, a drug formerly
22 prescribed to alleviate morning sickness, thalidomide, is an infamous teratogenic in humans, but
23 animal studies involving the drug failed to demonstrate such an increased risk of birth defects in
24 animals. GSK conducted studies of thalidomide and its toxicity before GSK developed Zofran
25 and before it marketed Zofran for the treatment of morning sickness in pregnant women.

26 Moreover, since at least 1993, GSK has stated in its prescribing information for Zofran that
27 “animal reproduction studies are not always predictive of human response.” Therefore, GSK has
28

1 been aware since at least when it began marketing and selling Zofran that GSK could not
2 responsibly rely on its animal studies as a basis for promoting Zofran use in pregnant women.

3 But that is what GSK did.

4 **2. Early Reports to GSK of Zofran-Related Birth Defects**

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

7
8 50. By 2000, GSK had received at least 32 reports of birth defects arising from Zofran
9 treatment in pregnant women. These reports included congenital heart disease, dysmorphism,
10 intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomaly, congenital
11 musculoskeletal anomalies, and orofacial anomalies, among others.

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

16
17 52. From 1992 to the present, GSK has received more than **200** reports of birth defects
18 in children who were exposed to Zofran during pregnancy.

19 53. The most commonly reported birth defects arising from Zofran use during
20 pregnancy and reported to GSK were congenital heart defects, though multiple other defects such
21 as orofacial defects, intrauterine death, stillbirth and severe malformations in newborns were
22 frequently reported.

23
24 54. The number of events actually reported to GSK was only a small fraction of the
25 actual incidents.

1 3. **Epidemiology Studies Examining the Risk of Congenital Heart Defects**
2 **in Babies Who Were Exposed to Zofran During Pregnancy**

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

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

13 57. Each of these studies includes methodological characteristics tending to bias its
14 results toward under-reporting the true risk of having a child with a birth defect. Notwithstanding
15 these characteristics biasing the results toward the null hypothesis, all three studies show elevated
16 risk ratios for cardiac malformations, including risk ratios greater than 2.0. In other words, the
17 studies report that a mother exposed to Zofran had more than a doubled risk of having a baby
18 with a congenital heart defect as compared to a mother who did not ingest Zofran during
19 pregnancy.
20

21 58. The Pasternak Study included data from the Danish National Birth Registry and
22 examined the use of Zofran during pregnancy and risk of adverse fetal outcomes. Adverse fetal
23 outcomes were defined as: spontaneous abortion, stillbirth, any major birth defect, pre-term
24 delivery, low birth weight, and small size for gestational age. There were 608,385 pregnancies
25 between January 2004 and March 31, 2011 examined. The unexposed group was defined as
26 women who did not fill a prescription for ondansetron during the exposure time window. The
27
28

1 exposure time window was defined as the first 12 week gestational period. Notably, the median
2 fetal age at first exposure to Zofran was ten weeks, meaning that half of the cases were first
3 exposed to Zofran after organogenesis (organ formation). This characteristic of the study led to
4 an under-reporting of the actual risk of prenatal Zofran exposure. The study's supplemental
5 materials indicated that women taking Zofran during the first trimester, compared to women who
6 did not take Zofran, were 22% more likely to have offspring with a septal defect, 41% more likely
7 to have offspring with a ventricular septal defect and greater than four-times more likely to have
8 offspring with atrioventricular septal defect.

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

25 60. The Danielsson Study investigated risks associated with Zofran use during
26 pregnancy and risk of cardiac congenital malformations from data available through the Swedish
27 Medical Birth Registry. The Swedish Medical Birth Registry was combined with the Swedish
28

1 Register of Prescribed Drugs to identify 1,349 infants born to women who had taken Zofran in
2 early pregnancy from 1998-2012. The total number of births in the study was 1,501,434 infants,
3 and 43,658 had malformations classified as major (2.9%). Among the major malformations,
4 14,872 had cardiovascular defects (34%) and 10,491 had a cardiac septum defect (24%). The
5 Danielsson study reported a statistically significantly elevated risk for cardiovascular defects for
6 mothers taking Zofran versus those who did not. The results reported that the mothers who took
7 Zofran during early pregnancy had a 62% increased risk of having a baby with a cardiovascular
8 defect. Further, mothers who took Zofran during pregnancy had a greater than two-fold increased
9 risk of having a baby with a septal cardiac defect, compared to mothers who did not take Zofran
10 during pregnancy.
11

12 61. In summary, since at least 1992, GSK has had mounting evidence showing that
13 Zofran presents an unreasonable risk of harm to babies who are exposed to the drug during
14 pregnancy. GSK has been aware that Zofran readily crosses human placental barriers during
15 pregnancy. GSK has also been aware that the animal studies of Zofran cannot reliably support an
16 assertion that Zofran can be used safely or effectively in pregnant women. Since 1992, GSK has
17 received hundreds of reports of major birth defects associated with prenatal Zofran exposure.
18 GSK also has had actual and/or constructive knowledge of the epidemiological studies reporting
19 that prenatal Zofran exposure can more than double the risk of developing congenital heart
20 defects. As alleged below, GSK not only concealed this knowledge from healthcare providers
21 and consumers in the United States, and failed to warn of the risk of birth defects, but GSK also
22 illegally and fraudulently promoted Zofran to physicians and patients specifically for the
23 treatment of morning sickness in pregnant women.
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1 4. **GSK’s Failure to Warn of the Risk of Birth Defects Associated with**
2 **Prenatal Exposure to Zofran**

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

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

8 64. In the context of prescription drug labeling, “an adverse reaction is an undesirable
9 effect, reasonably associated with use of a drug, that may occur as part of the pharmacological
10 action of the drug or may be unpredictable in its occurrence.” *Id.*

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

14 66. GSK has received hundreds of reports of birth defects associated with the non-
15 FDA-approved use of Zofran in pregnant women. GSK has failed, however, to disclose these
16 severe adverse events to healthcare providers or expectant mothers, including Ms. Murray and her
17 prescribing healthcare provider.
18

19 67. Under 21 C.F.R. § 314.70(c)(2)(i), pharmaceutical companies were (and are) free
20 to add or strengthen – without prior approval from the FDA – a contraindication, warning,
21 precaution, or adverse reaction.
22

23 68. GSK thus had the ability and obligation to add warnings, precautions and adverse
24 reactions to the product labeling for Zofran without prior approval from the FDA. GSK failed to
25 do so.
26

27 69. Under 21 C.F.R. § 201.128, “if a manufacturer knows, or has knowledge of facts
28 that would give him notice, that a drug introduced into interstate commerce by him is to be used

1 for conditions, purposes, or uses other than the ones for which he offers it, he is required to
2 provide adequate labeling for such a drug which accords with such other uses to which the article
3 is to be put.”

4 70. At least as of 1998, GSK knew well from its off-label promotion and payments to
5 doctors, its conspicuous increase in revenue from Zofran, and its market analyses of prescription
6 data, that physicians were prescribing Zofran off-label to treat morning sickness in pregnant
7 women and that such usage was associated with a clinically significant risk or hazard – birth
8 defects.

9
10 71. GSK had the ability and obligation to state prominently in the Indications and
11 Usage section of its drug label that there is a lack of evidence that Zofran is safe for the treatment
12 of morning sickness in pregnant women. GSK failed to do so, despite GSK’s knowledge that
13 (a) the safety of Zofran for use in human pregnancy has not been established, and (b) there have
14 been hundreds of reports of birth defects associated with Zofran use during pregnancy, and
15 (c) epidemiology studies report an increased risk of birth defects in babies exposed to Zofran
16 during pregnancy.

17
18 72. From 1993 to the present, despite mounting evidence of the birth defect risk,
19 GSK’s prescribing information for Zofran has included the same statement concerning use of
20 Zofran during pregnancy:

21
22 **“Pregnancy: Teratogenic Effects:** Pregnancy Category B. Reproduction studies have
23 been performed in pregnant rats and rabbits at I.V. doses up to 4 mg/kg per day and have
24 revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There
25 are, however, no adequate and well-controlled studies in pregnant women. Because
26 animal reproduction studies are not always predictive of human response, this drug should
27 be used during pregnancy only if clearly needed.”

28 73. 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.”**

1 74. In the United States, GSK has at all relevant times failed to include any warning
2 disclosing any risks of birth defects arising from Zofran use during pregnancy in Zofran’s
3 prescribing information or other product labeling.

4 75. GSK’s inclusion of the phrase “Pregnancy Category B” in Zofran’s prescribing
5 information refers the FDA’s pregnancy categorization scheme applicable to prescription drugs in
6 the United States. The FDA has established five categories to indicate the potential of a drug to
7 cause birth defects if used during pregnancy. The current system of pregnancy labeling consists
8 of five letter-categories (A, B, C, D, and X, in order of increasing risk).

9
10 76. GSK had the ability, and indeed was required, to update Zofran’s label to reflect at
11 best a Pregnancy Category D designation or alternatively a Category X designation for Zofran:

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

22 21 C.F.R. § 201.57(f)(6)(i)(d) (emphasis added).

23 **Pregnancy Category X. If studies in animals or humans have demonstrated fetal**
24 **abnormalities or if there is positive evidence of fetal risk based on adverse reaction**
25 **reports from investigational or marketing experience, or both, and the risk of the use**
26 **of the drug in a pregnant woman clearly outweighs any possible benefit (for example,**
27 **safer drugs or other forms of therapy are available), the labeling must state: “Pregnancy**
28 **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).

1 77. Beginning at least in 1992, GSK had positive evidence of human fetal risk posed
2 by Zofran based more than 200 reports to GSK of birth defects, as well as epidemiology studies,
3 and placental-transfer studies reporting on Zofran's teratogenic risk. GSK has never updated
4 Zofran's labeling to disclose that Zofran can cause fetal harm when administered to a pregnant
5 woman, and GSK has failed to warn of the potential hazards to a fetus arising from Zofran use
6 during pregnancy.
7

8 78. The FDA recently promulgated a final rule declaring that, as of June 2015, it will
9 begin requiring pharmaceutical manufacturers to remove the current A, B, C, D, or X pregnancy
10 categorization designation from all drug product labeling and instead summarize the risks of
11 using a drug during pregnancy, discuss the data supporting that summary, and describe relevant
12 information to help health care providers make prescribing decisions and counsel women about
13 the use of drugs during pregnancy and lactation. 79 Fed. Reg. 72064 (Dec. 4, 2014). In
14 promulgating this rule, the FDA "determined that retaining the pregnancy categories is
15 inconsistent with the need to accurately and consistently communicate differences in degrees of
16 fetal risk."
17

18 79. In summary, beginning years before Ms. Murray and J.M. were exposed to Zofran,
19 GSK marketed and sold Zofran without adequate warning to healthcare providers and consumers
20 that Zofran was causally associated with an increased risk of birth defects, and that GSK had not
21 adequately tested Zofran to support marketing and promotion it for use in pregnant women. This
22 rendered the warnings accompanying Zofran inadequate and defective.
23

24 80. Plaintiffs hereby demand that GSK immediately cease the wrongful conduct
25 alleged herein for the benefit of Plaintiffs and similarly situated mothers and mothers-to-be, as
26 GSK's wrongful conduct alleged herein is continuing. Plaintiffs further demand that GSK
27 promptly, fully and fairly comply to remove the Pregnancy Category B designation from its drug
28

1 product labeling for Zofran and fully and accurately summarize the risks of using Zofran during
2 pregnancy, fully and accurately describe the data supporting that summary, and fully and
3 accurately describe the relevant information to help health care providers make informed
4 prescribing decisions and counsel women about the risks associated with use of Zofran during
5 pregnancy.
6

7 **5. GSK's Fraudulent, Off-Label Promotion of Zofran for the Treatment**
8 **of Morning Sickness in Pregnant Women**

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

11 82. But with more than six million annual pregnancies in the United States since 1991
12 and an estimated 70-85% incidence of pregnancy-related nausea, the absence of a prescription
13 medication that was approved by the FDA for pregnancy-related nausea presented an extremely
14 lucrative business opportunity for GSK to expand its sales of Zofran. GSK seized that
15 opportunity, but the effect of its conduct was tantamount to experimenting with the lives of
16 unsuspecting mothers-to-be and their babies in the United States and in this State.

17 83. After the FDA approved Zofran in 1991, and despite available evidence showing
18 that Zofran presented an unreasonable risk of harm to babies exposed to Zofran prenatally, GSK
19 launched a marketing scheme to promote Zofran to obstetrics and gynecology (Ob/Gyn)
20 healthcare practitioners, among others, as a safe treatment alternative for morning sickness in
21 pregnant women.
22

23 84. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and
24 Communications (DDMAC) notified GSK that the FDA had become aware of GSK's
25 promotional materials for Zofran that violated the Federal Food Drug and Cosmetic Act and its
26 implementing regulations. The FDA reviewed the promotional material and determined that "it
27
28

1 promotes Zofran in a manner that is false or misleading because it lacks fair balance.” (FDA Ltr.
2 to Michele Hardy, Director, Advertising and Labeling Policy, GSK, Mar. 9 1999.)

3 85. GSK’s promotional labeling under consideration included promotional statements
4 relating the effectiveness of Zofran, such as “Zofran Can,” “24-hour control,” and other
5 promotional messages. But the promotional labeling failed to present any information regarding
6 the risks associated with use of Zofran.
7

8 86. In its March 9, 1999 letter, the FDA directed GSK to “**immediately cease**
9 **distribution of this and other similar promotional materials for Zofran that contain the**
10 **same or similar claims without balancing risk information.**”

11 87. GSK blatantly disregarded this mandate by the FDA. For example, in 2002,
12 GSK’s marketing materials to Ob/Gyn practitioners emphasized Zofran’s “Pregnancy Category
13 B” designation on the very first page of the marketing material, creating a false impression that
14 the safety of use in pregnancy has been established. GSK’s materials failed to disclose any of its
15 internal information concerning the risks of birth defects associated with Zofran treatment during
16 pregnancy.
17

18 88. GSK’s promotion of Zofran for use in pregnancy eventually led to a federal
19 governmental investigation. On July 2, 2012 the Department of Justice announced that GSK
20 “agreed to plead guilty and pay \$3 billion to resolve its criminal and civil liability arising from the
21 company’s unlawful promotion of certain prescription drugs,” which included Zofran among
22 numerous others. *See DOJ Press Release, GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to*
23 *Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012).*
24

25 89. Part of GSK’s civil liability to the government included payments arising from the
26 facts that: (a) GSK promoted Zofran and disseminated false representations about the safety and
27 efficacy of Zofran concerning pregnancy-related nausea and hyperemesis gravidarum, a severe
28

1 form of morning sickness; and (b) GSK paid and offered to pay illegal remuneration to health
2 care professionals to induce them to promote and prescribe Zofran.

3 **6. J.M.'s Exposure to Zofran**

4 90. Ms. Murray is the mother and natural guardian of J.M.

5 91. To alleviate the symptoms of morning sickness and prevent them from recurring,
6 Ms. Murray ingested Zofran beginning in her first trimester of pregnancy with J.M.
7

8 92. J.M. was born in 2007.

9 93. J.M. was diagnosed with congenital heart defects as a direct and proximate result
10 of her prenatal exposures to Zofran.

11 94. In particular, J.M. was born with an atrial septal defect. Consequently, J.M. has
12 undergone treatment, including a cardiac catheterization and placement of a septal occluder when
13 she was only four years old.
14

15 95. J.M. was exposed to Zofran in utero during the periods when each of the relevant
16 tissues was forming and susceptible to developmental insult from environmental exposure.

17 96. There is no known genetic cause for J.M.'s condition. There exists no family
18 history for any of the conditions from which J.M. suffers.

19 97. Ms. Murray was unaware of the dangerousness of Zofran or the fraudulent nature
20 of GSK's marketing of Zofran when she filled her prescriptions and took Zofran during
21 pregnancy.
22

23 98. Had Ms. Murray and/or her healthcare providers known of the increased risk of
24 birth defects associated with Zofran, she would not have taken Zofran during pregnancy and J.M.
25 would not have been born with congenital malformations.

26 99. As a direct and proximate result of GSK's conduct, Plaintiffs have suffered and
27 incurred harm including severe and permanent emotional and physical pain and suffering, mental
28

1 anguish, medical expenses and other economic and noneconomic damages, and J.M. will require
2 more constant and continuous medical monitoring and treatment than had she not been exposed to
3 Zofran.

4 100. Plaintiffs file this lawsuit within the applicable limitations period of first
5 suspecting and having reason to learn and discover that Zofran caused the appreciable harm
6 sustained by their daughter, J.M. Plaintiffs could not, by the exercise of reasonable diligence,
7 have discovered the wrongful cause of the injuries at an earlier time. Plaintiffs did not suspect,
8 nor did Plaintiff have reason to suspect, the tortious nature of the conduct causing the injuries,
9 until a short time before filing of this action.

10 101. Additionally, Plaintiffs were prevented from discovering this information sooner,
11 because GSK has misrepresented to the public and to the medical profession that Zofran is safe
12 for use in pregnancy, and GSK has fraudulently concealed facts and information that could have
13 led Plaintiffs to discover a potential cause of action.

14 102. In all events, the statute of limitations is tolled for claims arising from injuries to
15 minors.

16
17
18 **FIRST CAUSE OF ACTION**
19 **NEGLIGENCE**

20 103. Plaintiffs incorporate by reference herein each of the allegations set forth in this
21 Complaint as though set forth herein.

22 104. GSK had a duty to exercise reasonable care, and comply with existing standards of
23 care, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging,
24 sale, testing, and/or distribution of Zofran into the stream of commerce, including a duty to ensure
25 that the product would not cause users to suffer unreasonable, dangerous side effects.

26 105. GSK failed to exercise ordinary care and failed to comply with existing standards
27 of care in the designing, researching, manufacturing, marketing, supplying, promoting,
28

1 packaging, sale, testing, quality assurance, quality control, and/or distribution of Zofran into
2 interstate commerce in that GSK knew or should have known that using Zofran created an
3 unreasonable risk of dangerous birth defects, as well as other severe personal injuries which are
4 permanent and lasting in nature, physical pain and mental anguish, including diminished
5 enjoyment of life, embarrassment, loss of self-esteem, as well as the need for lifelong medical
6 treatment, monitoring and/or medications.
7

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

- 10 a. Failing to conduct adequate testing, including pre-clinical and clinical
11 testing and post-marketing surveillance to determine the safety risks of
12 Zofran for treating pregnant women while promoting the use of Zofran and
13 providing kickbacks to health care professionals to convince health care
14 professionals to prescribe Zofran for pregnancy-related nausea;
- 15 b. Marketing Zofran for the treatment of morning sickness in pregnant
16 women without testing it determine whether or not Zofran was safe for this
17 use;
- 18 c. Designing, manufacturing, producing, promoting, formulating, creating,
19 and/or designing Zofran without adequately and thoroughly testing it;
- 20 d. Selling Zofran without conducting sufficient tests to identify the dangers
21 posed by Zofran to pregnant women;
- 22 e. Failing to adequately and correctly warn Plaintiffs, the public, the medical
23 and healthcare profession, and the FDA of the dangers of Zofran for
24 pregnant women;
- 25 f. Failing to evaluate available data and safety information concerning Zofran
26 use in pregnant women;
- 27 g. Advertising and recommending the use of Zofran without sufficient
28 knowledge as to its dangerous propensities to cause birth defects;
- h. Representing that Zofran was safe for treating pregnant women, when, in
fact, it was and is unsafe;
- i. Representing that Zofran was safe and efficacious for treating morning
sickness and hyperemesis gravidarum when GSK was aware that neither
the safety nor efficacy for such treatment has been established;

- 1 j. Representing that GSK's animal studies in rats and rabbits showed no harm
2 to fetuses, when the data revealed impairment of ossification (incomplete
3 bone growth) and other signs of toxicity;
- 4 k. Failing to provide adequate instructions regarding birth defects including
5 cleft palate and cardiac malformations;
- 6 l. Failing to accompany Zofran with proper and/or accurate warnings
7 regarding all possible adverse side effects associated with the use of
8 Zofran;
- 9 m. Failing to include a black box warning concerning the birth defects
10 associated with Zofran;
- 11 n. Failing to issue sufficiently strengthened warnings following the existence
12 of reasonable evidence associating Zofran use with the increased risk of
13 birth defects;
- 14 o. Failing to advise Plaintiffs, their healthcare providers, FDA, and the
15 medical community that neither the safety nor the efficacy of Zofran for
16 treating pregnancy-related nausea has been established and that the risks of
17 the using the drug for that condition outweigh any putative benefit; and
- 18 p. Failing to advise Plaintiffs, their healthcare providers, FDA, and the
19 medical community of clinically significant adverse reactions (birth
20 defects) associated with Zofran use during pregnancy.

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

24 108. Reasonable manufacturers under the same or similar circumstances would have
25 warned of the dangers presented by Zofran, or instructed on the safe use of Zofran.

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

28 110. GSK's negligence was the proximate cause and substantial factor in causing of
Plaintiffs' injuries, harm and economic loss, which they suffered and/or will continue to suffer.

Had Ms. Murray not taken Zofran, J.M. would not have suffered her injuries and
damages as described herein with particularity.

1 112. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have
2 sustained and will continue to sustain severe physical injuries, severe emotional distress, mental
3 anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and
4 will continue to expend money for medical bills and expenses. Plaintiffs are entitled to
5 compensatory and equitable damages and declaratory relief in an amount to be proven at trial.
6

7 113. As a result of perceiving their daughter, J.M.'s injuries, Mr. and Ms. Murray
8 suffered serious emotional distress. Mr. and Ms. Murray witnessed J.M.'s injuries and treatment,
9 including a cardiac catheterization at the age of four, resulting from J.M.'s exposure to Zofran.
10 Although Mr. and Ms. Murray were unaware at the time of J.M.'s diagnosis and surgery that
11 Zofran had caused the injury, GSK's wrongful conduct was a substantial factor in causing Mr.
12 and Ms. Murray's serious emotional distress.
13

14 114. By reason of the foregoing, Plaintiffs and J.M. have been damaged by GSK's
15 wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to
16 the level of gross negligence so as to indicate a disregard of the rights and safety of others,
17 justifying an award of punitive damages.
18

19 **SECOND CAUSE OF ACTION**
20 **(NEGLIGENCE PER SE)**

21 115. Plaintiffs incorporate by reference herein each of the allegations set forth in this
22 Complaint as though set forth herein.

23 116. GSK had a duty to exercise reasonable care, and comply with existing laws, in the
24 designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing,
25 and/or distribution of Zofran into the stream of commerce, including a duty to ensure that the
26 product would not cause users to suffer unreasonable, dangerous side effects.

27 117. GSK failed to exercise ordinary care and failed to comply with existing laws in the
28 designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing,

1 quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that
2 GSK knew or should have known that using Zofran created an unreasonable risk of dangerous
3 birth defects, as well as other severe and personal injuries which are permanent and lasting in
4 nature, physical pain and mental anguish, including diminished enjoyment of life, embarrassment,
5 loss of self-esteem, as well as the need for lifelong medical treatment, monitoring and/or
6 medications.
7

8 118. GSK, its agents, servants, and/or employees, failed to exercise ordinary care and
9 violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.128, in
10 particular.
11

12 119. The laws violated by GSK were designed to protect Plaintiffs and similarly
13 situated persons and protect against the risks and hazards that have actualized in this case.
14 Therefore, GSK's conduct constitutes negligence per se.

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

18 121. GSK knew or should have known that consumers such as Plaintiffs would
19 foreseeably suffer injury as a result of GSK's failure to exercise ordinary care, as set forth above.
20

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

23 123. Had Ms. Murray not taken Zofran, J.M. would not have suffered the injuries and
24 damages as described herein.

25 124. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have
26 sustained and will continue to sustain severe physical injuries, severe emotional distress, mental
27 anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and
28

1 will continue to expend money for medical bills and expenses. Plaintiffs are entitled to
2 compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

3 125. By reason of the foregoing, Plaintiffs and J.M. have been damaged by GSK's
4 wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to
5 the level of gross negligence so as to indicate a disregard of the rights and safety of others,
6 justifying an award of punitive damages.
7

8 **THIRD CAUSE OF ACTION**
9 **(STRICT PRODUCTS LIABILITY—DESIGN DEFECT AND FAILURE TO WARN)**

10 126. Plaintiffs hereby incorporate by reference all previous paragraphs, as though
11 alleged fully in this Cause of Action.

12 127. GSK designed, formulated, produced, manufactured, sold, marketed, distributed,
13 supplied and/or placed Zofran into the stream of commerce. Zofran was defective at the time it
14 left GSK's control in that, and not by way of limitation, the drug failed to include adequate
15 warnings, instructions and directions relating to the dangerous risks associated with the use of
16 Zofran to treat pregnancy-related nausea. The Zofran sold to Ms. Murray also was defective in its
17 design because the foreseeable risks of harm posed by the product could have been reduced or
18 avoided by the adoption of a reasonable alternative design, failed to perform as safely as an
19 ordinary consumer would expect when used, and the benefits of the design and burden on GSK to
20 prevent harm did not outweigh the risk of danger and the gravity of the harm that was posed
21 Zofran's defective design.
22

23 128. Safe and effective products were available for the purpose for which GSK
24 marketed Zofran in pregnant women, and neither the safety nor the efficacy of Zofran for that
25 purpose had been established.
26
27
28

1 129. GSK failed to provide adequate warnings to physicians and users, including Ms.
2 Murray, of the increased risk of birth defects associated with Zofran and aggressively promoted
3 the product off-label to doctors, to hospitals, and directly to consumers.

4 130. Prescribing physicians, health care providers and mothers-to-be, neither knew, nor
5 had reason to know at the time of their use of Zofran of the existence of the aforementioned
6 defects. Ordinary consumers would not have recognized the potential risks or side effects for
7 which GSK failed to include appropriate warnings, and which GSK masked through unbalanced
8 promotion of Zofran specifically for treatment of pregnant women.

9 131. GSK's Zofran was expected to and did reach Plaintiffs and Plaintiffs' physicians
10 without substantial change in their condition as manufactured, distributed, and sold by GSK.

11 132. At all times herein mentioned, due to GSK's off-label marketing of Zofran, the
12 drug was prescribed and used as intended by GSK and in a manner reasonably foreseeable to
13 GSK.

14 133. The Zofran that was manufactured, distributed, and sold by GSK to Plaintiffs was
15 in a defective condition that was unreasonably and substantially dangerous to any users or
16 ordinary consumers of the drug for pregnancy-related nausea, such as Plaintiffs. Such ordinary
17 consumers, including Plaintiffs, would not and could not have recognized or discovered the
18 potential risks and side effects of Zofran.

19 134. GSK's design, manufacture, marketing, promotion, defense and sale of Zofran was
20 a substantial factor in causing Plaintiffs' injuries, as described herein.

21 135. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have
22 sustained and will continue to sustain severe physical injuries, severe emotional distress, mental
23 anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and
24

1 will continue to expend money for medical bills and expenses. Plaintiffs are entitled to
2 compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

3 136. By reason of the foregoing, Plaintiffs and J.M. have been damaged by GSK's
4 wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to
5 the level of gross negligence so as to indicate a disregard of the rights and safety of others,
6 justifying an award of punitive damages.
7

8 **FOURTH CAUSE OF ACTION**
9 **(INTENTIONAL MISREPRESENTATION)**

10 137. Plaintiffs incorporate by reference herein each of the allegations set forth in this
11 Complaint as though set forth herein.

12 138. GSK falsely and fraudulently represented to the expectant mothers and the medical
13 and healthcare community, including Ms. Murray and her providers, that:

- 14 a. Zofran was safe and effective for treating pregnancy-related nausea;
15 b. Zofran had been adequately tested and studied in pregnant women;
16 c. Zofran use during pregnancy did not increase the risk of bearing children
17 with birth defects; and
18 d. Zofran's "Pregnancy Category B" designation established the safety and
19 efficacy of Zofran for treating pregnancy-related nausea.

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

21 140. When GSK made these representations, it knew they were false, or made the
22 representations recklessly, without regard for their truth.

23 141. GSK made these representations with the intent of defrauding and deceiving the
24 public in general, and the medical and healthcare community in particular, and were made with
25 the intent of inducing the public in general, and the medical and healthcare community in
26 particular, including Ms. Murray and her providers, to recommend, prescribe, dispense and/or
27
28

1 purchase Zofran to treat pregnancy-related nausea, all of which evinced a callous, reckless,
2 willful, depraved indifference to the health, safety and welfare of Plaintiffs herein.

3 142. At the time the aforesaid representations were made by GSK and, at the time Ms.
4 Murray used Zofran, she was unaware of the falsity of said representations and reasonably
5 believed them to be true.

6 143. Plaintiffs and Plaintiffs' physicians justifiably relied to their detriment on GSK's
7 intentional and fraudulent misrepresentations as set out above. This reliance was a substantial
8 factor in and proximately caused the injuries and damages described in this Complaint.

9 144. In reasonable reliance upon said representations, Ms. Murray's prescribers were
10 induced to prescribe Zofran to her, and Ms. Murray was induced to and did use Zofran to treat
11 pregnancy-related nausea.

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

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

16 147. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have
17 sustained and will continue to sustain severe physical injuries, severe emotional distress, mental
18 anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and
19 will continue to expend money for medical bills and expenses. Plaintiffs are entitled to
20 compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

21 148. By reason of the foregoing, Plaintiffs and J.M. have been damaged by GSK's
22 wrongful conduct. GSK's conduct was willful, wanton, reckless, justifying an award of punitive
23 damages.

FIFTH CAUSE OF ACTION
(CONCEALMENT)

1
2
3 149. Plaintiffs incorporate by reference herein each of the allegations set forth in this
4 Complaint as though set forth herein.

5 150. In representations to Ms. Murray's healthcare providers, expectant mothers
6 including Ms. Murray and the FDA, GSK fraudulently concealed and intentionally omitted the
7 following material facts:

- 8 a. GSK was illegally paying and offering to pay doctors remuneration to
9 promote and prescribe Zofran;
- 10 b. Zofran had not (and has not) been tested or studied in pregnant women at
11 all;
- 12 c. *in utero* Zofran exposure increases the risk of birth defects;
- 13 d. the risks of birth defects associated with the consumption of Zofran by
14 pregnant women were not adequately tested prior to GSK's marketing of
Zofran;
- 15 e. the safety and efficacy of Zofran for treating pregnancy-related nausea has
16 not been established;
- 17 f. Zofran is not safe and effective for treating pregnancy-related nausea; and
- 18 g. GSK's internal data and information associated Zofran use during
19 pregnancy with birth defects.

20 151. GSK's concealment and omissions of material facts concerning, among other
21 things, the safety and efficacy of Zofran for pregnancy-related nausea was made purposefully,
22 willfully, wantonly, and/or recklessly, to mislead physicians, hospitals and healthcare providers,
23 and expectant mothers including Ms. Murray into reliance, continued use of Zofran, and to cause
24 them to promote, purchase, prescribe, and/or dispense Zofran.

25 152. Ms. Murray and her providers did not know the concealed facts described above.
26
27
28

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

4 154. Ms. Murray and her providers reasonably relied on GSK's promotional statements
5 concerning Zofran's asserted safety and efficacy in pregnant women, from which GSK
6 negligently, fraudulently and/or purposefully omitted material facts.

7 155. Had GSK disclosed the material facts described above, Ms. Murray reasonably
8 would not have taken Zofran.

9 156. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have
10 sustained and will continue to sustain severe physical injuries, severe emotional distress, mental
11 anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and
12 will continue to expend money for medical bills and expenses. Plaintiffs are entitled to
13 compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

14 157. GSK's concealment was a substantial factor in causing Plaintiffs' injuries.

15 158. By reason of the foregoing, Plaintiffs and J.M. have been damaged by GSK's
16 wrongful conduct. GSK's conduct was willful, wanton, reckless, so as to indicate a disregard of
17 the rights and safety of others, justifying an award of punitive damages.

18
19
20
21 **SIXTH CAUSE OF ACTION**
(NEGLIGENT MISREPRESENTATION)

22 159. Plaintiffs incorporate by reference herein each of the allegations set forth in this
23 Complaint as though set forth herein.

24 160. GSK falsely and negligently represented to the medical community and expectant
25 mothers, including Ms. Murray and her providers, that:

- 26
27 a. Zofran was safe and effective for treating pregnancy-related nausea;
28 b. Zofran had been adequately tested and studied in pregnant women;

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- 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.

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

162. GSK had no reasonable grounds for believing the aforementioned representations were true when made to the medical community and expectant mothers, including Ms. Murray and her providers.

163. As a direct and proximate result of GSK’s wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

164. By reason of the foregoing, Plaintiffs and J.M. 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.

**SEVENTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)**

165. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

166. Defendants expressly warranted that:

- a. Zofran was safe and effective for treating pregnancy-related nausea;
- b. Zofran had been adequately tested and studied in pregnant women;
- c. Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

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

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

8 168. Ms. Murray and her healthcare providers did rely on the express warranties of the
9 GSK herein.

10 169. Members of the medical community, including physicians and other healthcare
11 professionals, relied upon the representations and warranties of the GSK for use of Zofran in
12 recommending, prescribing, and/or dispensing Zofran to treat morning sickness.

13 170. GSK knew or should have known that, in fact, said representations and warranties
14 were false, misleading and untrue in that Zofran was not safe and fit for the use promoted,
15 expressly warranted and intended by GSK, and, in fact, it produced serious injuries to the
16 pregnant women and their babies, which injuries were not accurately identified and disclosed by
17 GSK.

18 171. Through sale of Zofran, Defendants are merchants pursuant to Section 2-314 of the
19 Uniform Commercial Code.

20 172. As a direct and proximate result of GSK's wrongful conduct, Plaintiffs have
21 sustained and will continue to sustain severe physical injuries, severe emotional distress, mental
22 anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and
23 will continue to expend money for medical bills and expenses. Plaintiffs are entitled to
24 compensatory and equitable damages and declaratory relief in an amount to be proven at trial.
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1 173. By reason of the foregoing, Plaintiffs and J.M. have been damaged by GSK’s
2 wrongful conduct. GSK’s conduct was willful, wanton, reckless, and, at the very least arose to
3 the level of gross negligence so as to indicate a disregard of the rights and safety of others,
4 justifying an award of punitive damages.
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6 **EIGHTH CAUSE OF ACTION**
7 **(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR**
8 **PARTICULAR USE)**

9 174. Plaintiffs incorporate by reference herein each of the allegations set forth in this
10 Complaint as though set forth herein.

11 175. GSK is a merchant with respect to goods of the kind Ms. Murray received. GSK
12 impliedly warranted that its product was merchantable. GSK impliedly warranted that its product
13 was fit for the particular purpose of being used safely in the treatment of pregnancy- related
14 nausea. Ms. Murray and her health care providers relied on GSK’s skill and judgment when
15 deciding to use GSK’s product.

16 176. GSK’s product was not fit for the ordinary purpose for which such goods were
17 used. It was defective in design and its failure to provide adequate warnings and instructions, and
18 was unreasonably dangerous. GSK’s product was dangerous to an extent beyond the expectations
19 of ordinary consumers with common knowledge of the product’s characteristics, including Ms.
20 Murray and her medical providers.

21 177. GSK breached its implied warranties because the product was not safe, not
22 adequately packaged and labeled, did not conform to representations GSK made, and was not
23 properly usable in its current form according to the labeling and instructions provided.
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25 178. As a direct and proximate result of GSK’s wrongful conduct, Plaintiffs have
26 sustained and will continue to sustain severe physical injuries, severe emotional distress, mental
27 anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and
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1 will continue to expend money for medical bills and expenses. Plaintiffs are entitled to
2 compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

3 179. By reason of the foregoing, Plaintiffs and J.M. have been damaged by GSK’s
4 wrongful conduct. GSK’s conduct was willful, wanton, reckless, and, at the very least arose to
5 the level of gross negligence so as to indicate a disregard of the rights and safety of others,
6 justifying an award of punitive damages.
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8 **NINTH CAUSE OF ACTION**
9 **(VIOLATION OF CAL. BUS. & PROF. CODE §§ 17200, ET SEQ. AND §§ 17500, ET**
10 **SEQ.)**

11 180. Plaintiffs hereby incorporate by reference all previous paragraphs, as though
12 alleged fully in this Cause of Action.

13 181. Plaintiffs bring this cause of action pursuant to California Business & Professions
14 Code §17204, in their individual capacities, and not on behalf of the general public.

15 182. California Business & Professions Code §17200 provides that unfair competition
16 shall mean and include “all unlawful, unfair or fraudulent business practices and unfair,
17 deceptive, untrue or misleading advertising.”

18 183. The acts and practices described in Paragraphs 1 through 88 above were and are
19 likely to mislead the general public, were conducted in California and elsewhere, and therefore
20 constitute unfair business practices within the meaning of Business & Professions Code
21 §17200. The acts of untrue and misleading advertising and marketing set forth in the preceding
22 paragraphs are incorporated by reference and are, by definition, violations of Business &
23 Professions Code §17200. This conduct includes, but is not limited to:
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- 25 a. Representing to Plaintiff, Plaintiff’s physicians and the general public that
26 Zofran was safe, fit and effective for morning sickness during pregnancy,
27 knowing that said representations were false, and concealing from the
28 Plaintiff, Plaintiff’s physicians and the general public that Zofran had a
serious propensity to cause birth defects;

- 1 b. Engaging in marketing and promotional efforts to create the image,
2 impression and belief by consumers, physicians and others that Zofran was
3 safe for use during pregnancy to treat morning sickness, even though GSK
4 knew this to be false, and even though GSK had no reasonable grounds to
5 believe this to be true;
- 6 c. Purposely downplaying and understating the health hazards and risks
7 associated with Zofran;
- 8 d. Failing to conduct sufficient testing of Zofran;
- 9 e. Withholding important safety information and critical product information
10 from the FDA, medical community and consumers;
- 11 f. Continuing to promote the use of the Zofran to physicians despite knowing
12 that there were increased risks of birth defects;
- 13 g. Failing to provide adequate warnings regarding the dangerous risks of
14 using Zofran during pregnancy; and
- 15 h. Actively, knowingly, and deceptively concealing its knowledge of its
16 product's dangerous properties and life-threatening risks.

17 184. These practices constitute unlawful, unfair and fraudulent business acts or
18 practices, within the meaning of California Business & Professions Code §17200, as well as
19 unfair, deceptive, untrue and misleading advertising as prohibited by California Business &
20 Professions Code §17500.

21 185. As a result of their conduct described above, GSK has been and will be unjustly
22 enriched.

23 186. Plaintiffs, pursuant to California Business & Professions Code §17203, seek an
24 order of this court compelling Defendants to disgorge the monies collected and profits realized by
25 them as a result of their unfair business practices.

26 187. Plaintiffs also seek injunctive relief pursuant to California Business & Professions
27 Code §§ 17204 and 17535. Specifically, Plaintiffs demand that GSK immediately cease the
28 wrongful conduct alleged herein for the benefit of Plaintiffs and similarly situated mothers and
 mothers-to-be. Plaintiffs have further demanded that GSK promptly, fully and fairly comply with

1 the FDA’s December 4, 2014 final rule referenced above and remove the Pregnancy Category B
2 designation from its drug product labeling for Zofran and fully and accurately summarize the
3 risks of using Zofran during pregnancy, fully and accurately describe the data supporting that
4 summary, and fully and accurately describe the relevant information to help health care providers
5 make informed prescribing decisions and counsel women about the risks associated with use of
6 Zofran during pregnancy.
7

8 **TENTH CAUSE OF ACTION**
9 **(DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION ACT, M.G.L. c.**
10 **93A, VIOLATIONS)¹**

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

14 189. GSK engaged in trade and commerce within the Commonwealth of Massachusetts.

15 190. Plaintiffs purchased and were exposed to Zofran within the Commonwealth of
16 Massachusetts.

17 191. The same actions that constitute GSK’s negligence, breach of warranty,
18 misrepresentations and concealment constitute a violation of M.G.L. c. 93A.

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

21 193. As described herein, GSK represented that its product was of a particular standard,
22 quality, and grade that they either knew or should have known was not of the standard, quality, or
23 grade described.
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27 ¹ 1. Plaintiffs have provided written notice under M.G.L. c. 93A, however 30 days has not yet
28 passed. Therefore, Plaintiffs will amend to add a specific reference to a violation of M.G.L. c.
93A once the required timeframe has elapsed.

1 194. GSK failed to provide accurate disclosures of all material information before
2 Plaintiff Katherine Murray and her providers transacted to use GSK's product.

3 195. GSK's willful and knowing withholding of important safety information and
4 critical product information constitutes a violation of M.G.L. c. 93A.

5 196. GSK actively, knowingly, and deceptively concealed its knowledge of its
6 product's dangerous properties and risks. This conduct evidences bad faith and unfair and
7 deceptive practices.

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

10 198. The practices described herein are unfair because they offend public policy as
11 established by statutes, the common law, or otherwise and caused substantial injury to consumers.
12 In this regard, GSK engaged in an unconscionable course of action.

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

16 200. GSK is liable to Plaintiffs for all statutory, direct and consequential damages, and
17 fees and costs, resulting from this unfair and deceptive conduct, including multiple damages.

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21 **DEMAND FOR JURY TRIAL**

22 Plaintiffs demand trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure
23 and the Seventh Amendment of the U.S. Constitution.

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25 **PRAYER FOR RELIEF**

26 201. WHEREFORE, Plaintiffs demand judgment against GSK on each of the above-
27 referenced claims and Causes of Action and as follows:
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- a. For general (non-economic) damages according to proof at the time of trial in a sum in excess of the jurisdictional minimum of this Court;
- b. For special (economic) damages according to proof at the time of trial;
- c. For pre-judgment interest as provided by law;
- d. For disgorgement of all revenue that GSK obtained through design, promotion, marketing, manufacture, sale and administration of Zofran;
- e. 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;
- f. For attorneys’ fees, expenses and costs of this action; and
- g. For such further and other relief as this Court deems necessary, just and proper.

Dated: September 29, 2015

Respectfully submitted,

By: /s/ Elizabeth J. Cabraser
 Elizabeth J. Cabraser

**LIEFF CABRASER HEIMANN &
 BERNSTEIN, LLP**
 Elizabeth J. Cabraser
 Sarah R. London
 275 Battery St., 29th Floor
 San Francisco, CA 94111
 Telephone: (415) 956-1000
 Facsimile: (415) 956-1008

**LIEFF CABRASER HEIMANN &
 BERNSTEIN, LLP**
 250 Hudson Street, 8th Floor
 New York, NY 10013-1413
 Telephone: (212) 355-9500
 Facsimile: (212) 355-9592