UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	)	**MDL 2342**
	)	**12-MD-2342**
	)	**HON. CYNTHIA M. RUFE**
Ember Alexis Chupp, a minor, by Cassie Chupp, Mother and Natural Guardian,	)	**CASE NO. _____**
Plaintiffs,	)	**COMPLAINT**
	)	**JURY TRIAL DEMANDED**
vs.	)	
PFIZER, INC. AND PFIZER INTERNATIONAL LLC,	)	
Defendants.	)	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, Cassie Chupp, as Mother and Natural Guardian on behalf of Ember Alexis Chupp, a Minor ("Minor Plaintiff") (collectively "Plaintiffs") by and through their undersigned counsel, hereby submit this Complaint against Defendants PFIZER, INC. and PFIZER INTERNATIONAL LLC (collectively "Pfizer" or "Defendants") and allege as follows:

STATEMENT OF THE CASE

1. Pfizer develops, designs, manufactures, promotes, markets and sells the drug Zoloft. Pfizer markets Zoloft as a drug to treat, among other things, depression, anxiety, obsessive-compulsive disorder and panic attacks. Pfizer does not know how Zoloft allegedly helps those suffering from these conditions.

2. In early animal testing of the drug before it was sold for human consumption, Pfizer learned that Zoloft, if taken during pregnancy, caused birth defects, particularly heart defects, clubfoot and fetal death.

3. Pfizer began selling Zoloft to the public in 1992. Pfizer never tested Zoloft's effects on pregnant women or their unborn children. In its promotional activities, Pfizer did not discourage the use of Zoloft in pregnant women. In fact, through a variant of methods, Pfizer actually encouraged doctors to prescribe Zoloft to women of childbearing age, women who were trying to conceive and even to pregnant women. Pfizer also directly marketed Zoloft to these women.

4. By 2005, Zoloft was the most prescribed anti-depressant with over 27 million prescriptions filled and $3.3 billion in sales.

5. Cassie Chupp was prescribed and took Zoloft during the first trimester of her pregnancy in 2004. Because she and her doctor did not know Zoloft could cause birth defects, including bilateral club foot, she continued taking it during her pregnancy.

6. On November 18, 2004, during a prenatal ultrasound, doctors told Cassie Chupp that her daughter, Ember, had bilateral talipes equinovarus, commonly known as bilateral clubbed foot.

7. On March 18, 2005, Cassie Chupp gave birth to her daughter, Ember Alexis Chupp.

8. Immediately after birth, Ember's prenatal diagnosis of bilateral club foot was confirmed by the physicians.

9. As a result of Ember's congenital birth defect Ember underwent a series of corrective treatments, including multiple surgeries.

10. Ember began being followed by an orthopedic surgeon immediately upon her birth for treatment of her bilateral club foot. At that time, Ember began corrective treatment in the form of serial casting. This corrective treatment continued until Ember was approximately six months old.

11. On December 12, 2005, Ember Alexis Chupp underwent a bilateral posteromedial and posterolateral clubfoot releases.

12. On May 7, 2008, Ember underwent her second corrective procedure, specifically bilateral anterior tibialis transfer, cuboid osteotomy without IF and bilateral above-the-knee fiberglass casts.

13. On August 8, 2012, Ember underwent another procedure, specifically bilateral distal tibia/fibula osteotomies with internal fixation, left cuboid closing wedge osteotomy and application of bilateral below-knee casts.

14. As a baby and throughout her childhood, Ember's doctors have closely monitored her bilateral clubbed foot. Her monitoring continues yearly and will follow her for her entire life.

15. To this day, Pfizer has not informed women of childbearing age or even pregnant women that they should not take Zoloft. Pfizer still targets these women as their primary market.

PARTIES AND JURISDICTION

16. PFIZER, INC. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in the State of New York. Pfizer regularly conducts business in the States of Pennsylvania, Georgia and throughout the United States and derives substantial revenues from drugs it sells in the States of Pennsylvania, Georgia and throughout the United States. Pfizer is engaged in the business of designing, developing,

manufacturing, promoting, marketing, distributing and selling pharmaceutical drugs, including the drug Zoloft® (Generically known as Sertraline) in Pennsylvania, Georgia and throughout the United States.

17. Pfizer may be served with process by registered mail with return receipt requested, upon CT Corporation System, 111 Eighth Avenue, New York, New York, 10011. However, on October 17, 2012 this Court issued Stipulation and Joint Pretrial Order 12: Waiver of Service stating that PFIZER, INC. provides the following address to which Rule 4(d) requests for waiver should be sent via certified mail: CT Corporation System, 116 Pine Street, 3rd Floor, Suite 320, Harrisburg, Pennsylvania, 17101.

18. PFIZER INTERNATIONAL LLC ("Pfizer International") is a corporation organized and existing under the laws of the State of New York with its principal place of business in the State of New York. Pfizer International regularly conducts business in the States of Pennsylvania, Georgia and throughout the United States and derives substantial revenues from drugs it sells in the States of Pennsylvania, Georgia and throughout the United States. Pfizer International is engaged in the business of designing, developing, manufacturing, promoting, marketing, distributing and selling pharmaceutical drugs, including the drug Zoloft (Generically known as Sertraline) in Pennsylvania, Georgia and throughout the United States.

19. Pfizer International may be served with process by registered mail with return receipt requested, upon CT Corporation System, 111 Eighth Avenue, New York, New York, 10011.

20. Pfizer, Inc. is incorporated under the laws of Delaware and has its principal place of business in New York; therefore, it is a citizen of Delaware and New York under 28 U.S.C. §1332(c)(1). Pfizer International LLC is incorporated under the laws of New York and has its principal place of business in New York.

21. Plaintiff, Cassie Chupp, is a citizen of Georgia for purposes of bringing this action as the legal representative of Minor Plaintiff, Ember Alexis Chupp. Plaintiffs are citizens of Georgia under 28 U.S.C. §1332(c)(2).

22. Plaintiffs seek damages in excess of seventy-five thousand dollars ($75,000.00) exclusive of interests and costs.

23. This Court has subject matter jurisdiction based on diversity of citizenship, 28 U.S.C. §1332.

24. Venue is proper in this Court under 28 U.S.C. §1391 because at all times relevant to this Complaint, Pfizer has engaged in continual business in this District and, for purposes of venue, is deemed to reside in this District under 28 U.S.C. §1391(c).

25. Venue is also proper in this Court pursuant to 28 U.S.C. §1407 and the consolidation of related cases into In Re: Zoloft (Sertraline Hydrochloride) Products Liability Litigation, MDL No. 2342, pursuant to Court order dated April 17, 2012.

26. This Court allowed for direct filing into the MDL in Case Management Order No. 11, which was entered on October 17, 2012. If this Court did not allow for direct filing into the MDL, this case would have been filed in the federal court in which the Plaintiffs reside.

FACTUAL ALLEGATIONS

27. Pfizer designed, developed, manufactured, marketed, promoted and sold Zoloft.

28. Zoloft is a selective serotonin reuptake inhibitor (SSRI) marketed, primarily, as an antidepressant medication.

29. Pfizer does not know the mechanism of action by which Zoloft treats depression or other disorders. Pfizer, in its marketing, claims that Zoloft's effect on serotonin in the brain is a potential mechanism through which Zoloft treats depression and other disorders.

30. Pfizer also promotes Zoloft as a treatment for obsessive-compulsive disorder, panic attacks, posttraumatic stress disorder and anxiety disorders.

31. In 2005, Zoloft was the most prescribed antidepressant drug on the U.S. retail market with almost 27 million prescriptions dispensed. In 2005, Zoloft's sales totaled $3.3 billion.

32. Upon information and belief, Cassie Chupp's healthcare providers prescribed Zoloft and Cassie began taking Zoloft in approximately January 2004 and continued taking it into her pregnancy through July 2004.

33. Minor Plaintiff, Ember Alexis Chupp, was born on March 18, 2005 at Southern Regional Medical Center in Riverdale, Georgia.

34. After the birth of her daughter, Cassie Chupp's doctors confirmed the prenatal diagnosis that her daughter had blateral talipes equinovarus, commonly known as bilateral clubbed foot, and would require treatment of a nature to be determined.

35. As a result of Ember's congenital birth defect Ember underwent a series of corrective treatments, including multiple surgeries.

36. Ember began being followed by an orthopedic surgeon immediately upon her birth for treatment of her bilateral club foot. At that time, Ember began corrective treatment in the form of serial casting. This corrective treatment continued until Ember was approximately six months old.

37. On December 12, 2005, Ember Alexis Chupp underwent a bilateral posteromedial and posterolateral clubfoot releases.

38. On May 7, 2008, Ember underwent her second correct procedure, specifically bilateral anterior tibialis transfer, cuboid osteotomy without IF and bilateral above-the-knee fiberglass casts.

39. On August 8, 2012, Ember underwent another procedure, specifically bilateral distal tibia/fibula osteotomies with internal fixation, left cuboid closing wedge osteotomy and application of bilateral below-knee casts.

40. Throughout her entire childhood, Ember Alexis Chupp has suffered physically and emotionally from her birth defect caused by Zoloft. Ember continues to have regular medical treatment, including but not limited to orthopedic exams and testing and has been deprived of living a normal childhood and life.

PFIZER KNEW OR SHOULD HAVE KNOWN THAT ZOLOFT CAUSES SERIOUS BIRTH DEFECTS

41. Plaintiffs incorporate the paragraphs above as if set forth herein.

42. Prior to initial approval in 1991, Pfizer's preclinical animal studies demonstrated significant harm to animal fetuses when Zoloft was administered during pregnancy, including increased mortality and birth defects.

43. Pfizer knew about these adverse side effects, yet, without further testing, Pfizer began marketing and selling Zoloft to healthcare providers and the public.

44. In its promotional activities, however, Pfizer did not discourage the use of Zoloft in pregnant women. In fact, through a variety of methods, Pfizer actually encouraged doctors and other healthcare providers to prescribe Zoloft to women of childbearing age, women who were trying to conceive and even to pregnant women.

45. After Pfizer had been selling the drug for years, concerned independent scientists began studies to determine whether Zoloft and other SSRI drugs caused birth defects. Pfizer could have, but did not perform these studies. These studies showed that Zoloft causes serious birth defects when ingested during pregnancy. These defects include, but are not limited to, ventricular septal defects, atrial septal defects, hypoplastic left or right heart syndrome, total anomalous pulmonary venous return, craniosynostosis, omphalocele, gastroschisis, persistent pulmonary hypertension of the newborn (PPHN), Tetralogy of Fallot, pulmonary atresia, limb deformations (including bilateral club foot), spina bifida, cleft palate, and patent ductus arteriosis.

46. In September 2005, the manufacturers of the SSRI drug Paxil, a drug very similar to Zoloft, added language to their drug's label warning doctors and patients of cardiac malformations and other structural birth defects when Paxil is ingested during pregnancy.

47. Pfizer had no justifiable reason to believe that Zoloft was materially less likely to cause birth defects than Paxil.

48. Yet, Pfizer did not modify its label to warn of these dangers, and in fact, increased its targeted promotion to women of childbearing years to capture the now vulnerable population of women who could no longer take Paxil.

49. Many observational studies show a statistically significant increase in birth defects associated with the use of Zoloft.

50. In 2006, the New England Journal of Medicine published a scientific study showing a causal relationship between the use of SSRIs during pregnancy, including Zoloft, and babies being born with PPHN which is a serious heart defect. The scientists who authored this

study found that pregnant women who took SSRIs after the 20th week of pregnancy were six times more likely to have babies with PPHN than infants born to mothers who did not take SSRIs during their pregnancies.

51. In June 2007, the New England Journal of Medicine published another study showing that, compared to babies of women who did not take SSRIs during pregnancy, babies of women who took Pfizer's Zoloft during pregnancy had a 50% higher risk of developing heart defects [HR 1.5 (95% CI: .9-2.6)].

52. Another study published in June 2007 in the New England Journal of Medicine found that babies of women who ingested Zoloft were twice as likely to be born with septal heart defects than those who were born without the influence of Zoloft [HR 2.0 (95% CI: 1.2-4.0]. This statistically significant result shows a clear doubling of the risk when Zoloft was in the mother's system as the baby developed.

53. In September 2009, the British Medical Journal published a population based cohort study that had over 493,000 patients. This study found that Zoloft carried an increased risk for congenital heart defects with a statistically significant tripling of risk [OR 3.25 (95% CI: 1.21-8.75)]. This same study also revealed a doubling of the risk of major malformations of the infant, including cranial malformations, when mothers were exposed to serataline during pregnancy [OR 1.51 (95% CI: 0.84-2.69)].

54. In August 2010, an article published in Clinical Epidemiology detailed the results of a population based prevalence study conducted in Denmark that included over 216,000 women. This study found that Zoloft carries an increased risk of cardiac malformations with a statistically significant odds ratio of 3.0 [OR 3.0 (95% CI: 1.4-6.4)]. This indicates that the risk of a baby having a cardiac malformation when Zoloft is in the mother's system is more than

triple that of babies whose mothers did not ingest Zoloft. This same study also revealed a more than tripling of the risk of septal heart defects in babies whose mothers ingested Zoloft during pregnancy [OR 3.3 (95% CI: 1.5-7.5)]. This finding was also statistically significant.

55. Upon information and belief, there was a study presented at an international conference in Taipei, Taiwan in the Fall of 2014 which reflected a statistically significant association between a mother's use of Zoloft during pregnancy and the birth of a child with club foot. This confirms an earlier finding by Carol Louik of an association in 2007.

56. Additional studies were published in 2007 and later that examined other birth defects that occurred when mothers ingested Zoloft during pregnancy. These included a statistically significant, almost six-fold risk of a baby being born with omphalocele (a condition where the newborn's intestine or abdominal organs are protruding from the abdomen) and an increased risk of a baby being born with craniosynostosis (a condition where the skull bones and plates fuse earlier than normal resulting in increased pressure inside the skull) when a mother ingested Zoloft during her pregnancy.

57. The current Zoloft label still does not warn healthcare providers or patients about the increased risk of birth defects seen in babies whose mothers took Zoloft.

PFIZER CONCEALED THE RISKS OF ZOLOFT FROM THE PUBLIC, THE MEDICAL COMMUNITY AND THE FOOD & DRUG ADMINISTRATION IN VIOLATION OF THE FEDERAL REGULATIONS

58. Plaintiffs incorporate the paragraphs above as if set forth herein.

59. To date, Pfizer has failed to adequately warn or inform consumers, such as Plaintiffs and Cassie Chupp's prescribing healthcare providers, of the known effects of Zoloft that can lead to heart malformations and other birth defects, such as bilateral club foot.

60. Pfizer fraudulently concealed these effects and made misrepresentations to the damage and detriment of Plaintiffs.

61. Many of the studies conducted by Pfizer failed to demonstrate efficacy for Zoloft in treating adults, children and adolescents and revealed significant and serious side effects. Pfizer sought to limit healthcare providers' access to the negative data and promoted only the most favorable aspects of the data from these studies.

62. Pfizer took actions to suppress and conceal negative information concerning the drug and to consciously misrepresent the data it did reveal concerning the drug's efficacy and safety. These actions by Pfizer include, but are not limited to:

a) "Ghostwriting" letters and articles for the signature of key opinion leaders to be placed in respected medical journals;

b) suppressing information about Zoloft's adverse effects;

c) promoting positive study outcomes while avoiding negative ones; and

d) communicating marketing messages designed to persuade healthcare providers to prescribe Zoloft, particularly to women of childbearing years.

63. In 2005, the United States Food and Drug Administration, ("FDA") issued a warning letter to Pfizer citing it for omitting risk information about Zoloft and for placing advertisements that were false and misleading to the public. The FDA stated, "This ad is concerning from a public health perspective because it fails to include a serious risk associated with the drug." In addition, the FDA issued other warning letters to Pfizer due to its violations in promotional materials and activities, including a letter dated August 1, 1996.

64. The FDA makes it illegal to receive, introduce, or deliver for introduction into interstate commerce any drug that is "misbranded." 21 U.S.C. §331(a)-(c).

A. A drug is misbranded if any one of several circumstances exists, such as:

1) False or Misleading. A drug is misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. §352(a).

2) Prominence. A drug is misbranded if required information is not prominently placed with such conspicuousness and in such terms as to make it likely to be read and understood by an ordinary individual. 21 U.S.C. §352(c).

3) Truth in Advertising. A prescription drug is misbranded if its advertising does not provide a "true statement" with respect to side effects, contraindications, or effectiveness. 21 U.S.C. §352(n). Advertising cannot be "false, lacking in fair balance, or otherwise misleading." 21 C.F.R. §202.1(e).

B. It will be so deemed if, for example, it:

1) Contains a representation or suggestion, not approved for use in the labeling, that the drug is better, safer, more effective, or effective in a broader range of conditions than demonstrated by substantial evidence. 21 C.F.R. §202.1(e)(6)(i);

2) Contains an unsupported comparative claim or superiority claim. 21 C.F.R. §202.1(e)(6)(i) and (ii).

3) Contains unsupported favorable information or opinions. 21 C.F.R. §202.1(e)(6)(iii);

4) Selectively presents favorable information on safety or side effects. 4521 C.F.R. §202.1(e)(6)(iv);

5) Suggests that study information has more general application. 4621 C.F.R. §202.1(e)(6)(v);

6) Uses literature references that do not support the claim in question. 4721 C.F.R. §202.1(e)(6)(vi).

7) Uses data that have no clinical significance. 4821 C.F.R. §02.1(e)(6)(vii).

8) Uses statements from authorities out of context, or ignoring negative or inconsistent views. 4921 C.F.R. §202.1(e)(6)(viii)-(ix);

9) Uses literature, quotations, or references to recommend or suggest an unapproved indication or to inaccurately support an approved indication. 21 C.F.R. §202.1(e)(6)(x) – (xi); or

10) Cites scientific studies that are defective in construction or contain criteria making them inapplicable to the sponsor's purpose. 5121 C.F.R. §202.1(e)(6)(xiii)-(xx).

11) As alleged herein, as a direct and proximate result of the Defendants' negligence and wrongful conduct, including violations of the federal regulations, and the unreasonably dangerous and defective characteristics of the subject product, the Plaintiffs suffered severe and permanent physical and emotional injuries which are continuing in nature.

PFIZER CONTINUES TO MISREPRESENT THE SAFETY AND EFFICACY OF ZOLOFT

65. Plaintiffs incorporate the paragraphs above as if fully set forth herein.

66. Despite Pfizer's longstanding knowledge of the danger of birth defects, Pfizer failed, and continues to fail, to warn and disclose to consumers that Zoloft significantly increases the risk of heart malformations and other birth defects, such as bilateral club foot. Furthermore, the proper and effective use of Zoloft by Cassie Chupp was impaired due to Pfizer's failure to warn of Zoloft's defects and Pfizer's failure to properly and adequately set forth such warnings in Zoloft's drug labeling.

67. Pfizer knew of the dangerous birth defects associated with Zoloft use during pregnancy from the preclinical studies and the subsequently published studies confirming these risks. Pfizer took no action to properly study Zoloft and did not properly publish the results of studies it did do, which would have reflected that risk. Pfizer failed to adequately warn or remedy the risks, but instead concealed, suppressed and failed to disclose the dangers. Even in the face of the numerous published studies, Pfizer continues to deny these dangers and will not revise its drug labeling.

TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

68. Plaintiffs incorporate the paragraphs above as if fully set forth herein.

69. Plaintiffs assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, fraudulent concealment and/or minority tolling.

70. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury and the tortuous nature of the wrongdoing that caused the injury.

71. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages and their relationship to Zoloft was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit is being filed well within the applicable statutory limitations period.

72. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Cassie Chupp's healthcare providers of the true risks associated with taking Zoloft. As a result of Defendants' fraudulent concealment, Plaintiffs and Cassie Chupp's prescribing healthcare providers were unaware and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

73. The running of the statute of limitations in this cause may be tolled due to the pendency of a class action proceeding against Defendants herein. Class Action tolling is proper where Plaintiffs are members of an asserted class and the claims asserted in the class action proceeding are the same as the claims asserted in this action.

74. The statute of limitations is tolled due to the minority of the Plaintiff. This action is being filed within the applicable statutory period before related to minority tolling.

75. The statute of limitations is tolled due to the disability of Plaintiffs. Plaintiffs were under one or more of the following recognized disabilities: mental illness, infancy, insanity, inability to comprehend the nature of legal proceedings, imprisonment, absence from the state due to government service or other legal disability recognized by the applicable state law.

76. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection between the injury and Defendants' tortuous conduct.

COUNT ONE – STRICT PRODUCTS LIABILITY – FAILURE TO WARN

77. Plaintiffs incorporate the paragraphs above as if fully set forth herein.

78. Pfizer is liable to Plaintiffs for the negligent and/or willful failure to provide adequate warnings and other clinically relevant information and data regarding the appropriate use of Zoloft to the Plaintiffs and Cassie Chupp's prescribing healthcare proviers.

79. Pfizer, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Pfizer knew or should have known that the warnings and other clinically relevant information and data which they distributed regarding the risks of congenital birth defects associated with the use of Zoloft were inadequate.

80. Plaintiffs and Cassie Chupp's prescribing healthcare providers did not have the same knowledge as Pfizer and no adequate warning or other clinically relevant information and data was communicated to Plaintiffs or to Cassie Chupp's prescribing healthcare providers.

81. Pfizer had a continuing duty to provide consumers, including Plaintiffs and their healthcare providers, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Zoloft as it became or could have become available to Pfizer.

82. Pfizer designed, developed, manufactured, marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Zoloft, in the stream of commerce to healthcare providers empowered to prescribe and dispense Zoloft to consumers, including Cassie Chupp, without adequate warnings and other clinically relevant information and data. Through both omissions and affirmative misstatements, Pfizer misled the medical community about the risks and benefits of Zoloft, which resulted in injury to Plaintiffs, specifically Ember Alexis Chupp's congenital birth defect.

83. Despite the fact that Pfizer knew or should have known that Zoloft caused unreasonable and dangerous side effects, including congenital birth defects, they continued to manufacture, market, promote, distribute and sell Zoloft without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

84. Pfizer marketed Zoloft by way of direct to consumer (DTC) advertisements in Pennsylvania, Georgia and throughout the United States.

85. Pfizer knew or should have known that consumers and Plaintiffs specifically, would foreseeably and needlessly suffer injury as a result of Pfizer's failures.

86. Pfizer breached their duty to provide timely and adequate warnings, instructions and information, in the following particulars:

a) failing to ensure Zoloft warnings to the medical community, physicians, including Cassie Chupp's prescribing healthcare providers, and Plaintiffs were accurate and adequate despite having extensive knowledge of the risks associated with Zoloft;

b) failing in their obligation to provide the medical community, physicians, including Cassie Chupp's healthcare providers, and Plaintiffs with adequate clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Zoloft and/or that there existed safer and more or equally effective alternative drug products;

c) failing to conduct post market safety surveillance and report that information to the medical community, including Cassie Chupp's healthcare providers and Plaintiffs;

d) failing to include adequate warnings and/or providing adequate and clinically relevant information and data that would alert the medical community, including Cassie Chupp's healthcare providers, and Plaintiffs to the dangerous risks of Zoloft, including, among other things, the association with congenital birth defects;

e) failing to continually monitor, test and analyze data regarding safety, efficacy and prescribing practices of their marketed drugs, including Zoloft;

f) failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy or safety, including the risks and/or prevalence of side effects caused by Zoloft to the medical community, including Cassie Chupp's healthcare providers and Plaintiffs;

g) failing to provide adequate post-marketing warnings and instructions after Pfizer knew or should have known of the significant risks of, among other things, congenital birth defects of Zoloft;

h) failing to periodically review all medical literature regarding Zoloft and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy or safety of Zoloft;

i) failing to disclose the results of the testing and other information in their possession regarding the possibility that Zoloft can interfere with the proper development of an unborn fetus; and

j) failing to warn adequately the medical community, the general public and Plaintiffs of the dangers of using Zoloft during pregnancy, including the risk of congenital birth defects; and/or representing that Zoloft was safe for use during pregnancy, when in fact, Pfizer knew or should have known that Zoloft was unsafe for this use and that Zoloft was associated with congenital birth defects.

87. Pfizer continued to aggressively design, develop, manufacture, market, promote, distribute and sell Zoloft, even after they knew or should have known of the unreasonable risks of congenital birth defects from Zoloft.

88. Pfizer had an obligation to provide Plaintiffs and Cassie Chupp's healthcare providers with adequate and clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there existed safer and more or equally effective alternative drug products.

89. By failing to provide Plaintiffs and Cassie Chupp's healthcare providers with adequate, clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or to inform them that there existed safer and more or equally effective alternative drug products, Pfizer breached their duty of reasonable care and safety.

90. As a direct and proximate result of the actions and inactions of Pfizer as set forth above, Plaintiffs were exposed to Zoloft, as a result suffered and continue to suffer, the injuries and damages, as set forth herein.

91. WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $75,000.00, compensatory damages, punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT TWO – STRICT PRODUCTS LIABILITY – DESIGN DEFECT

92. Plaintiffs incorporate the paragraphs above as if fully set forth herein.

93. Pfizer designed, developed, manufactured, marketed, promoted, distributed and sold Zoloft in the stream of commerce which was:

a) unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risks of congenital birth defects;

b) defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of Zoloft;

c) defective in design, making use of Zoloft more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Cassie Chupp's underlying condition;

d) defective in design, making use of Zoloft more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;

e) defective in design in that Zoloft contained insufficient, incorrect, and defective warnings in that they failed to alert healthcare providers and users, including Plaintiffs, of the risks of adverse effects; and/or

f) defective in design in that Zoloft was not safe for its intended use and was inadequately tested.

94. Pfizer knew and intended that Zoloft would be used by consumers, including Cassie Chupp, without any inspection for defects and that Cassie Chupp and her healthcare providers would rely upon the representations made by Pfizer on Zoloft's product labels and otherwise.

95. Prior to the manufacturing, promotion, sale and distribution of Zoloft, Pfizer knew, or was reckless in not knowing, that Zoloft was in a defective condition.

96. Cassie Chupp used Zoloft for its intended purpose and could not have discovered any defect therein through the exercise of due care.

97. At the time that Pfizer designed, developed, manufactured, marketed, promoted, distributed and sold Zoloft there existed safer and more or equally effective alternative drug products.

98. As a direct and proximate result of the actions and inactions of Pfizer as set forth above, Plaintiffs were exposed to Zoloft, and as a result, suffered and continue to suffer, injuries and damages, as set forth herein.

99. WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $75,000.00, compensatory damages, punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT THREE – BREACH OF WARRANTY – IMPLIED AND EXPRESS

100. Plaintiffs incorporate the paragraphs above as if fully set forth herein.

101. At all times hereinafter mentioned, upon information and belief, Pfizer, by direct and indirect advertising, marketing and promoting Zoloft for the treatment of depression and other conditions in women, including women of childbearing potential and pregnant women, placed Zoloft in the stream of commerce knowing that Zoloft would be prescribed to pregnant women in reliance upon the representations or omissions of Pfizer and expressly warranted to all foreseeable users of Zoloft, including Cassie Chupp and Cassie Chupp's healthcare providers, that Zoloft was safe and effective for the treatment of women of child bearing age and during pregnancy and without significant risk to the fetus.

102. Pfizer impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Zoloft to all foreseeable users, including Cassie Chupp and Cassie Chupp's healthcare providers, that Zoloft was safe and effective for the purposes for which it had

been placed in the stream of commerce by Pfizer, including for the treatment of depression and other conditions during pregnancy, and that Zoloft was reasonably safe, proper, merchantable and fit for its intended purpose, including for the treatment of pregnant women and without significant risk to the fetus.

103. At all time relevant hereto, Plaintiffs and Cassie Chupp's healthcare providers relied upon the aforesaid express and implied warranties by Pfizer.

104. Cassie Chupp's use of Zoloft and Cassie Chupp's healthcare providers' prescribing of Zoloft was consistent with the purposes for which Pfizer directly and indirectly advertised, marketed and promoted Zoloft. Cassie Chupp's use of Zoloft and Cassie Chupp's healthcare providers' prescribing of Zoloft was reasonably contemplated, intended and foreseen by Pfizer at the time of the distribution and sale of Zoloft by Pfizer. Therefore, Cassie Chupp's use of Zoloft was within the scope of the above-described express and implied warranties.

105. Pfizer breached the aforesaid express and implied warranties because Zoloft was not safe and effective for the treatment of depression and other conditions in women during pregnancy because it exposed the developing fetus to a significant risk of serious injury, and because Cassie Chupp's use of Zoloft for treatment during her pregnancy caused the Minor Plaintiff's birth defect, bilateral club foot.

106. As a direct and proximate result of Pfizer's breach of express and implied warranties, Plaintiffs suffered severe and permanent physical injuries which are continuing in nature, as set forth herein.

107. WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $75,000.00, compensatory damages, punitive damages, together with interest, costs of suit, attorney fees and all other such relief as the Court deems proper in an amount to be determined upon the trial of this matter.

COUNT FOUR – NEGLIGENCE

108. Plaintiffs incorporate paragraphs above as if fully set forth herein.

109. At all times mentioned herein, Pfizer was under a duty to exercise reasonable care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, design, manufacturing, marketing, packaging, producing, promoting, processing, researching, selling and testing Zoloft to ensure that use of Zoloft did not result in avoidable injuries.

110. Pfizer knew or should have known that Zoloft was not safe for use during pregnancy and that the pregnant user and unborn child could sustain injuries and harm from the drug.

111. At all times relevant to this lawsuit, Pfizer owed a duty to consumers, including Plaintiffs and Cassie Chupp's healthcare providers, to assess, manage and communicate the risks, dangers and adverse effects of Zoloft, and to warn the medical community, consumers, the Plaintiffs and Cassie Chupp's healthcare providers of those risks, dangers and adverse effects.

112. Pfizer's duties included, but were not limited to, carefully and properly advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling and testing Zoloft, which was placed in the stream of commerce, and providing adequate information regarding the appropriate use of Zoloft.

113. Pfizer negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care. Pfizer failed to fulfill the above-stated duty by directly and indirectly advertising, marketing and promoting Zoloft for the treatment of depression and other conditions during pregnancy, even though Zoloft is not reasonably safe for such use. Furthermore, Pfizer failed to adequately warn of the increased risk of serious birth defects which Pfizer knew or should have known about.

114. The injuries sustained by the Plaintiffs were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness and conscious and callous disregard for the safety of the public, including Plaintiffs, on the part of Pfizer in the design, manufacture, distribution, advertising, marketing and promoting of Zoloft as being safe and effective in the treatment of depression and other conditions, and by inducing the public, including Cassie Chupp and her prescribing healthcare providers, to believe that Zoloft was effective for the treatment of depression, bipolar disorder and other conditions during pregnancy.

115. Pfizer failed to exercise reasonable care in the above-described duties to Plaintiffs by committing negligent acts and/or omissions, including, but not limited to, the following:

a) failing to ensure Zoloft's warnings to the medical community, physicians, including Cassie Chupp's healthcare providers, and Plaintiffs were accurate and adequate, despite having extensive knowledge of the risks associated with Zoloft;

b) failing to adequately test the product prior to placing the drug Zoloft on the market;

c) failing in their obligation to provide the medical community, physicians, including Cassie Chupp's healthcare providers, and Plaintiffs with adequate and clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there existed safer and more or equally effective alternative drug products;

d) failing to conduct post market safety surveillance and report that information to the medical community, physicians, including Cassie Chupp's healthcare providers, and Plaintiffs;

e) failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, physicians, including Cassie Chupp's healthcare providers, and Plaintiffs to the dangerous risks of Zoloft;

f) failing to continually monitor, test and analyze data regarding safety, efficacy, and the prescribing practices for Zoloft;

g) failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy or safety, including the risks and/or prevalence of side effects caused by Zoloft to the medical community, physicians, including Cassie Chupp's healthcare providers, and Plaintiffs;

h) failing to provide adequate post-marketing warnings and instructions after Pfizer knew or should have known of the significant risks of, among other things, congenital birth defects of Zoloft;

i) failing to periodically review all medical literature regarding Zoloft and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of its warnings, efficacy or safety of Zoloft;

j) failing to disclose the results of the testing and other information in their possession regarding the risk that Zoloft can interfere with the proper development of an unborn fetus;

k) failing to warn adequately the medical community, physicians, including Cassie Chupp's healthcare providers, and Plaintiffs of the dangers of using Zoloft during pregnancy, including the risk of congenital birth defects;

l) representing that Zoloft was safe for use during pregnancy when, in fact, Pfizer knew or should have known that Zoloft was unsafe for this use and that Zoloft was associated with congenital birth defects;

m) promoting and marketing Zoloft for use with pregnant women, despite the fact that the Pfizer knew or should have known that Zoloft was associated with an increased risk of congenital abnormalities;

n) promoting and marketing Zoloft as safe and effective for use with pregnant women when, in fact, it was unsafe;

o) promoting and marketing Zoloft for non-approved (off-label) uses and/or illegally over-promoting, marketing, advertising, and selling Zoloft in a zealous and unreasonable way, without regard to the potential danger that it posed for an unborn fetus;

p) failing to independently monitor their sales of Zoloft and the medical literature, which would have alerted them to the fact that Zoloft was widely over-prescribed to women of childbearing potential as a result of inadequate warnings in the package inserts and PDR monographs for Zoloft, and as a result of the over-promotion of Zoloft;

q) failing to act as a reasonably prudent drug manufacturer in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, selling and testing Zoloft;

r) failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Zoloft's use;

s) failing to use ordinary care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packaging, producing, promoting, processing, researching, selling and testing Zoloft so as to reveal and communicate the risk of congenital birth defects to the medical community, including Cassie Chupp's healthcare providers, and Plaintiffs;

t) failing to accompany Zoloft with adequate information that would alert the medical community, including Cassie Chupp's healthcare providers, and Plaintiffs to the potential adverse side effects associated with the use of Zoloft and the nature, severity and duration of such adverse effects;

u) failing to conduct adequate post-marketing studies, non-clinical and clinical testing, and post-marketing surveillance and analyses to determine and communicate the safety profile and side effects of Zoloft;

v) continuing to promote the safety and effectiveness of Zoloft, while downplaying their risks, even after Pfizer knew or should have known of the risks of Zoloft;

w) failing to provide consumers, such as Plaintiffs and Cassie Chupp's healthcare providers, with scientific data which indicated that Zoloft was unreasonably dangerous, and that there were no women of childbearing potential and/or pregnant women in whom the benefits of Zoloft outweighed the risks;

x) being careless and negligent in that Pfizer knew or should have known that Zoloft was a substance that would be actively transported through the placenta during pregnancy and could inhibit the health and development of the fetus;

y) negligently and carelessly promoting Zoloft as safe and effective for use with women of childbearing potential and/or pregnant women when, in fact, it was unsafe;

z) negligently and carelessly over-promoting Zoloft in a zealous and unreasonable way, without regard to the potential danger that it posed to an unborn fetus; and/or

aa) negligently and carelessly failing to act as a reasonably prudent drug manufacturer, distributor, marketer, promoter or seller would under same or similar circumstances.

116. Although Pfizer knew or should have known that Zoloft caused unreasonably dangerous side effects, including congenital birth defects, Pfizer continued to market Zoloft, despite the fact there were safer and more or equally effective alternative drug products.

117. Pfizer knew or should have known that consumers, such as Plaintiffs, would suffer injury as a result of Pfizer's failure to exercise ordinary care, as described above.

118. The conduct of Pfizer was a direct and proximate cause of Plaintiffs' injuries. Pfizer knew or should have known that Zoloft posed a risk and was dangerous and unsafe for the developing fetus.

119. As a direct and proximate result of the negligent acts and/or omissions of Pfizer as set forth above, Plaintiffs suffered, and will continue to suffer into the future, injuries and damages, as set forth herein.

120. WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $75,000.00, compensatory and punitive damages, together with interest, costs of suit, attorney fees and all other such relief as the Court deems proper in an amount to be determined upon the trial of this matter.

COUNT FIVE – FRAUDULENT MISREPRESENTATION AND CONCEALMENT

121. Plaintiffs incorporate paragraphs above as if fully set forth herein.

122. Pfizer is liable to Plaintiffs for fraudulently, intentionally and/or negligently misrepresenting to the public, and to Plaintiffs, both directly and by and through Cassie Chupp's prescribing healthcare providers, the safety and effectiveness of Zoloft when used by pregnant women and/or women of childbearing potential, and/or fraudulently, intentionally and/or negligently concealing, suppressing or omitting material, adverse information regarding the safety and effectiveness of Zoloft when used by pregnant women and/or women of childbearing potential.

123. Pfizer's fraudulent, intentional and/or negligent material misrepresentations and omissions regarding the safety and efficacy of Zoloft and of Zoloft's side effects, including the risk of congenital birth defects, were communicated to Plaintiffs directly through promotional materials, advertising, product inserts and the monograph provided with Cassie Chupp's prescription with the intent that Cassie Chupp would ingest Zoloft. The safety and efficacy of Zoloft was also fraudulently, intentionally and/or negligently misrepresented to Cassie Chupp's prescribing healthcare providers with the intent that such misrepresentations would cause Zoloft to be prescribed to Cassie Chupp.

124. Pfizer either knew or should have known that the material representations they were making regarding Zoloft's safety, efficacy and side effects were false.

125. Pfizer fraudulently, intentionally and/or negligently made the misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce Cassie Chupp to ingest Zoloft and to induce Cassie Chupp's healthcare providers to prescribe Zoloft. Pfizer fraudulently, intentionally and/or negligently

knew or should have known that Cassie Chupp, Cassie Chupp's healthcare providers and the consuming public would rely on such material misrepresentations and/or omissions in selecting Zoloft for the treatment of Cassie Chupp. Pfizer knew or should have known that Cassie Chupp and Cassie Chupp's healthcare providers would rely upon their false representations and/or omissions.

126. Pfizer made these material misrepresentations and/or omissions and actively concealed adverse information at a time when they, their agents and/or their employees knew or should have known that Zoloft had defects, dangers and characteristics that were other than what had been represented to the medical community and the consuming public, including the Plaintiffs herein. Those misrepresentations and omissions further include, but are not limited to, the following particulars:

a) Pfizer failed to disclose or concealed that their pre-clinical and clinical testing, and post-marketing surveillance was inadequate to determine the safety and side effects of Zoloft;

b) Pfizer failed to disclose or concealed data showing that Zoloft increased the risk of congenital birth defects;

c) Pfizer failed to include adequate warnings with Zoloft about the potential and actual risks, and nature, scope, severity and duration of any serious side effects of this drug, including, without limitation, the increased risk of congenital birth defects, other injuries and death, either compared to the use of alternative drug products in its class or compared to the use of no drug products; and/or

d) Pfizer concealed and continues to conceal past and present facts, including that as early as the 1990's, Pfizer was aware of and concealed their knowledge of an association between the use of Zoloft and dangerous side effects, including the increased risk of congenital birth defects, from the consuming public, including Plaintiffs and Cassie Chupp's healthcare providers.

127. Pfizer's material misrepresentations and/or active concealment, suppression and omissions were perpetuated directly and/or indirectly by Pfizer, their sales representatives, employees, distributors, agents and/or detail persons, through the databases, printouts, monographs and other information drafted, prepared, marketed, sold and supplied by Pfizer, their sales representatives, employees, distributors, agents and/or detail persons.

128. Pfizer's material misrepresentations and/or active concealment, suppression, and omissions constitute a continuing tort.

129. Through its product inserts, Pfizer continued to misrepresent the potential risks and complications associated with Zoloft.

130. Pfizer had a post-sale duty to warn healthcare providers and Plaintiffs about the potential risks and complications associated with Zoloft they manufactured and sold in a timely manner.

131. Pfizer fraudulently, intentionally and/or negligently misrepresented the safety and efficacy of Zoloft in their labeling, advertising, product inserts, promotional materials or other marketing.

132. If Plaintiffs and Cassie Chupp's healthcare providers had known the true facts concerning the risks of Zoloft, in particular, the risk of congenital birth defects, they would not have prescribed and used Zoloft, and would have instead prescribed and used one of the safer alternatives, or no drug.

133. Plaintiffs' and Cassie Chupp's healthcare providers' reliance upon the Pfizer's material misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Zoloft, while Plaintiffs and Plaintiff's healthcare providers were not in a

position to know the true facts, and because Pfizer overstated the benefits and safety of Zoloft, and concomitantly downplayed the risks of its use, including congenital birth defects, thereby inducing Cassie Chupp and Cassie Chupp's healthcare providers to use Zoloft, in lieu of other, safer alternatives or no drug at all.

134. As a direct and proximate result of the Plaintiffs' and Cassie Chupp's healthcare providers' reliance on Pfizer's misrepresentations and concealment concerning the risks and benefits of Zoloft, Plaintiffs suffered injuries and damages, as set forth herein.

135. WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $75,000.00, compensatory damages, punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT SIX – NEGLIGENT MISREPRESENTAION

136. Plaintiffs incorporate the paragraphs above as if fully set forth herein.

137. After Pfizer became aware of the risks of ingesting Zoloft during pregnancy, Pfizer failed to communicate to Cassie Chupp, her healthcare providers and other members of the general public that the ingestion of this drug while pregnant had an increased risk of serious birth defects.

138. Pfizer failed to warn the Plaintiffs, and other consumers, of the defective condition of Zoloft, as manufactured and/or supplied by Pfizer.

139. Pfizer, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Zoloft in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such

misrepresentations. Alternatively, Pfizer made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

140. The above misrepresentations were made to Cassie Chupp, her healthcare providers as well as to the general public. Cassie Chupp and her healthcare providers justifiably relied on Pfizer's misrepresentations.

141. Cassie Chupp's ingestion of Zoloft was to her detriment and to the detriment of her daughter, Ember. Pfizer's negligent misrepresentations proximately caused the Plaintiffs' injuries and monetary losses.

142. WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $75,000.00, compensatory damages, punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT SEVEN – NEGLIGENCE PER SE

143. Plaintiffs incorporate the paragraphs above as if fully set forth herein.

144. Pfizer has an obligation to not violate the law.

145. Pfizer has violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., related amendments and codes and federal regulations promulgated thereunder, and other applicable state and federal laws as alleged herein.

146. Plaintiffs as a purchaser and consumers of Zoloft, is within the class of persons that statues described above are designed to protect.

147. Injury due to false, misleading and/or reckless advertising, promotion and misbranding, and as otherwise set forth in this Complaint, is the specific type of harm these statutes are designed to prevent.

148. Pfizer is responsible to Plaintiffs for injuries incurred for its violations of statutes described above under the doctrine of negligence per se.

149. As a direct and proximate result of the negligence and negligence per se of Pfizer and as a result of Pfizer's actions and/or inactions as set forth in this Complaint, the Plaintiffs were caused to suffer severe and permanent physical and emotional injuries as alleged herein.

150. WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $75,000.00, compensatory damages, punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT EIGHT – UNJUST ENRICHMENT

151. Plaintiffs incorporate the paragraphs above as if fully set forth herein.

152. As an intended and expected result of its conscious wrongdoing, Defendants have profited and benefited from the purchases of Zoloft by Cassie Chupp.

153. Defendants have voluntarily accepted and retained these profits and benefits, derived from Cassie Chupp and others, with full knowledge and awareness that, as a result of Defendants fraud and other conscious and intentional wrongdoing, Cassie Chupp did not receive a product of the quality, nature or fitness that had been represented by the Defendants or that she, as a reasonable consumer, expected.

154. By virtue of the conscious wrongdoing alleged herein, Defendants have been unjustly enriched at the expense of Ember Alexis Chupp, who is entitled to in equity, and hereby seeks the disgorgement and restitution of Defendants' wrongful profits, revenue and benefits, to the extent, and in the amount, deemed appropriate by the Court, and such other relief as this Court deems just and proper to remedy the Defendants' unjust enrichment.

155. WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $75,000.00, compensatory damages, punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

COUNT NINE – PUNITIVE DAMAGES

156. Plaintiffs incorporate the paragraphs above as if fully set forth herein.

157. At all times material hereto Defendants' actions were reckless and without regard for the public's safety and welfare.

158. The Defendants knowingly withheld, concealed or misrepresented the risks and dangers of Zoloft and the Zoloft information and warnings, including the risk of congenital birth defects, from both the medical community and the public at large, including Plaintiffs, their healthcare providers and their pharmacists. The Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Zoloft, including congenital birth defects, despite information demonstrating Zoloft was unreasonably dangerous and in conscious disregard of the risk of serious injury posed to Plaintiffs by these known misrepresentations and/or omissions.

159. At all times material hereto, Pfizer had a duty to exercise reasonable care in the advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling and/or testing Zoloft.

160. The conduct of Pfizer in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling and/or testing Zoloft, and in

failing to warn Plaintiffs, Cassie Chupp's healthcare providers, pharmacists and other members of the public of the dangers inherent in the use of Zoloft during pregnancy, which were known to the Defendants, was attended by circumstances of fraud, malice or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiffs.

161. Pfizer knew that Zoloft had unreasonably dangerous risks and caused serious side effects of which Plaintiffs, their healthcare providers and pharmacists would not be aware. Pfizer nevertheless advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packaged, produced, promoted, processed, researched, sold and tested Zoloft knowing that there were safer methods and products available.

162. Pfizer's misrepresentations include knowingly withholding material information from the medical community, the public, including Cassie Chupp, and the FDA concerning the safety of the subject product.

163. Pfizer knew of Zoloft's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable harm caused by Zoloft.

164. Pfizer intentionally concealed and/or recklessly failed to disclose to the medical community, the public, including the Plaintiffs herein, and the FDA the potentially life threatening side effects and birth defects associated with the use of Zoloft during pregnancy in order to ensure continued and increased sales.

165. Pfizer's intentional and/or reckless failure to disclose information deprived Cassie Chupp and her prescribing healthcare providers of necessary information to enable them to weigh the true risks of using Zoloft during pregnancy against its benefits.

166. As a direct and proximate result of Pfizer's conscious and deliberate disregard for the rights and safety of consumers such as Plaintiffs, Ember Alexis Chupp suffered severe and permanent physical injuries, including but not limited to bilateral club foot and the treatment thereof, including but not limited to serial casting, bilateral posteromedial and posterolateral releases; bilateral tendon transfer with bilateral above-the-knee fiberglass casts; and bilateral tibia/fibula osteotomies with internal fixation, left cuboid closing wedge osteotomy and bilateral below-knee casts. Plaintiffs endured conscious pain and suffering, both physical and emotional in nature. Significant expenses were incurred for the medical care and treatment of Ember Alexis Chupp. Plaintiffs have suffered severe pecuniary loss and seek actual and punitive damages from Pfizer as alleged herein.

167. The Defendants' actions were performed willfully, deliberately, intentionally and with reckless disregard for the rights and safety of Plaintiffs and the public and caused substantial injury.

168. The conduct of the Defendants, undertaken with knowledge, for these purposes, evinces gross negligence and a willful, wanton and conscious disregard for the rights and safety of consumers, including the Plaintiffs, and as a direct and proximate result of the Defendants' actions and inactions, Plaintiffs suffered injuries due to Defendants' disregard for Plaintiffs' rights and safety, and therefore, Plaintiffs are entitled to an award of punitive damages from Pfizer.

169. WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $75,000.00, compensatory damages, punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

JURY DEMAND

Plaintiffs demand that all issues of fact and all counts in this case be tried to a properly empanelled jury.

CONCLUSION AND PRAYER

WHEREFORE, Plaintiffs request trial by jury and that the Court grants them the following relief against the Defendants, on all counts of this Complaint, including:

(A) Compensatory Damages, including but not limited to, past, present and future pain and suffering, representing fair, just, and reasonable compensation for their respective common law and statutory claims in excess of $75,000.00, exclusive of interests and costs;

(B) Punitive Damages;

(C) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;

(D) Costs of suit and expenses; and

(E) Such other relief as is deemed just and appropriate.

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFFS

Dated: March , 2015

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

CMR 15 1184

The JS 44 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, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

John Mark Harrleson and Allison Nicole Harrelson, Individually and as Personal Representatives of the Estate of McKinley C. Harrelson, Deceased

(b) County of Residence of First Listed Plaintiff Lexington County, SC
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Kimberly D. Barone Baden, Esq., Fred Thompson, III, Esq., Ann E. Rice Ervin, Esq./Motley Rice LLC/28 Bridgeside Blvd., Mt. Pleasant, SC 29464 and Rosemary Pinto, Esq./Feldman Pinto/1604 Locust St. #2R, Philadelphia, PA 19103

DEFENDANTS

Pfizer, Inc., Pfizer International LLC and Greenstone LLC f/k/a Greenstone Limited

County of Residence of First Listed Defendant Manhattan
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 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)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 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

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities Employment
- ☐ 446 Amer. w/Disabilities Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. 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)* ☒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. 1332 and 28 U.S.C. 1407

Brief description of cause:
Zoloft Birth Defect MDL Litigation

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Cynthia M. Rufe DOCKET NUMBER MDL No. 2342

DATE 3/5/2015 SIGNATURE OF ATTORNEY OF RECORD

MAR - 9 2015

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

CMR

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 125 Hillview Rd., Hampton, GA 30228

Address of Defendant: 235 42nd St., New York, NY 10017 (as to Pfizer)

15 1184

Place of Accident, Incident or Transaction: Georgia

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☒ as to Plaintiffs Unknown as to Defendants

Does this case involve multidistrict litigation possibilities? Yes☒ No☐

RELATED CASE, IF ANY:

Case Number: 12-MDL-2342 Judge Cynthia M. Rufe Date Terminated: Active case

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☒ No☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases

(Please specify) _____

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases

(Please specify) _____

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Kimberly D.Barone Baden, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

MAR - 9 2015

DATE: 3/5/15 Kimberly D. Barone Baden Pro Hac Vice

Attorney-at-Law Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 3/5/15 Kimberly D. Barone Baden Pro Hac Vice

Attorney-at-Law Attorney I.D.#

CIV. 609 (5/2012)

CMR

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Ember Alexis Chupp, a minor, by Cassie Chupp, Mother and Natural Guardian	:	
	:	CIVIL ACTION NO.
vs.	:	MDL NO. 2342
	:	15 1184
Pfizer, Inc. and Pfizer International LLC	:	

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

3/5/2015 _____ _____

Date **Attorney-at-law**

Attorneys for Plaintiffs

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(Phone) (215) 546-2604 (Fax) (215) 546-9904

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